EXHIBIT 2

S

Supreme Court of Pennsylvania

Court of Common Pleas
Civil Cover Sheet

Clearfield County **County**

For Prothonotary Use Only:	FILED
Docket No: 2020-1026-CD	AUG 21 2020 BRIAN K. SPENCER PROTHONOTARY & CLERK OF COURTS

The information collected on this form is used solely for court administration purposes. This form does not supplement or replace the filing and service of pleadings or other papers as required by law or rules of court.

SECTION A

Commencement of Action:
☒ Complaint ☐ Writ of Summons ☐ Petition
☐ Transfer from Another Jurisdiction ☐ Declaration of Taking

Lead Plaintiff's Name:	Lead Defendant's Name:
District Attorney of Clearfield County	Purdue Pharma, LP
Are money damages requested? ☒ **Yes** ☐ **No**	Dollar Amount Requested: (check one) ☐ within arbitration limits ☒ outside arbitration limits
Is this a *Class Action Suit*? ☐ **Yes** ☒ **No**	**Is this an *MDJ Appeal*?** ☐ **Yes** ☒ **No**

Name of Plaintiff/Appellant's Attorney: Gabriel C. Magee, Esquire

☐ **Check here if you have no attorney (are a Self-Represented [Pro Se] Litigant)**

SECTION B

Nature of the Case: Place an "X" to the left of the **ONE** case category that most accurately describes your ***PRIMARY CASE.*** If you are making more than one type of claim, check the one that you consider most important.

TORT (*do not include Mass Tort*)
- ☐ Intentional
- ☐ Malicious Prosecution
- ☐ Motor Vehicle
- ☐ Nuisance
- ☐ Premises Liability
- ☒ Product Liability (*does not include mass tort*)
- ☐ Slander/Libel/ Defamation
- ☐ Other:

MASS TORT
- ☐ Asbestos
- ☐ Tobacco
- ☐ Toxic Tort - DES
- ☐ Toxic Tort - Implant
- ☐ Toxic Waste
- ☐ Other:

PROFESSIONAL LIABLITY
- ☐ Dental
- ☐ Legal
- ☐ Medical
- ☐ Other Professional:

CONTRACT (*do not include Judgments*)
- ☐ Buyer Plaintiff
- ☐ Debt Collection: Credit Card
- ☐ Debt Collection: Other
- ☐ Employment Dispute: Discrimination
- ☐ Employment Dispute: Other
- ☐ Other:

REAL PROPERTY
- ☐ Ejectment
- ☐ Eminent Domain/Condemnation
- ☐ Ground Rent
- ☐ Landlord/Tenant Dispute
- ☐ Mortgage Foreclosure: Residential
- ☐ Mortgage Foreclosure: Commercial
- ☐ Partition
- ☐ Quiet Title
- ☐ Other:

CIVIL APPEALS
Administrative Agencies
- ☐ Board of Assessment
- ☐ Board of Elections
- ☐ Dept. of Transportation
- ☐ Statutory Appeal: Other
- ☐ Zoning Board
- ☐ Other:

MISCELLANEOUS
- ☐ Common Law/Statutory Arbitration
- ☐ Declaratory Judgment
- ☐ Mandamus
- ☐ Non-Domestic Relations Restraining Order
- ☐ Quo Warranto
- ☐ Replevin
- ☐ Other:

Updated 1/1/2011

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Plaintiff

v.

PURDUE PHARMA L.P.
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201 Tresser Boulevard
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AND
PURDUE PHARMA INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
AND
THE PURDUE FREDERICK COMPANY, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
AND
TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, Pennsylvania 19454
AND
CEPHALON, INC.

COURT OF COMMON PLEAS
CLEARFIELD COUNTY, PA
CIVIL ACTION – LAW

JURY TRIAL DEMANDED

1090 Horsham Road :
North Wales, Pennsylvania 19454 :
AND :
JOHNSON & JOHNSON :
1 Johnson & Johnson Plaza :
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AND :
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1125 Trenton Harbouton Road :
Titusville, New Jersey 08560-0200 :
AND :
NORAMCO, INC. :
By and through its Registered Agent: The :
Corporation Trust Company, Corporation Trust :
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AND :
ENDO PHARMACEUTICALS, INC. :
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AND :
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AND :
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INC. :
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:
:

AND :
McKESSON CORPORATION :
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San Francisco, CA 94104 :
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AND :
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AND :
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AND :
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By and through its Registered Agent: :
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AND :
RHODES PHARMACEUTICALS, INC. :
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AND :
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AND :
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AND :
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AND :
ALLERGAN FINANCE LLC :
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AND :

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AND

WATSON LABORATORIES, INC.
By and through its Registered Agent: Corporate Creations Network, Inc., 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, DE 19810

AND

ACTAVIS, LLC
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AND

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Ireland

AND

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AND

SPECGX LLC
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AND

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AND

CVS PHARMACY INC.
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AND :
CVS INDIANA LLC :
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AND :
CVS RX SERVICES, INC. :
1 CVS Dr, Woonsocket, RI 02895 :
AND :
CVS TN DISTRIBUTION, LLC :
1 CVS Dr, Woonsocket, RI 02895 :
AND :
CVS OF PENNSYLVANIA, INC. :
1 CVS Dr, Woonsocket, RI 02895 :
AND :
CVS PA DISTRIBUTION, L.L.C. :
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AND :
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RITE AID DRUG PALACE INC :
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Corporation Trust Company, Corporation Trust :
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AND :
RITE AID OF PENNSYLVANIA, INC :
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Corporation Trust Company, Corporation Trust :
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AND :
RITE AID OF PENNSYLVANIA, LLC :
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AND :
GIANT EAGLE, INC. :
101 Kappa Dr., Pittsburgh, PA 15238 :
AND :

GIANT EAGLE DRUGS :
55th St. & A.V.R.R., Pittsburgh, PA 15201 :
AND :
AHOLD USA INC :
1149 Harrisburg Pike, Carlisle, PA 17013 :
AND
THE GIANT COMPANY LLC
1149 Harrisburg Pike, Carlisle, PA 17013
AND
WAL-MART INC.,
By and through its Registered Agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801
Defendants.

NOTICE TO PLEAD

NOTICE You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER (OR CANNOT AFFORD ONE), GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. **PENNSYLVANIA BAR ASSOCIATION** LAWYER REFERRAL SERVICE: 1-800-692-7375

THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

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AVISO Le han demandado en corte. Si usted quiere defenderse contra las demandas nombradas en las paginas siquientes, tiene veinte (20) dias a partir de recibir esta demanda notificacion para entablar personalmente o por un abogado una comparesencia escrita y tambien para entablar con la corte en forma escrita sus defensas y objeciones a las demandas contra usted sin previo aviso para conseguir el deniro demandado en el pleito o para conseguir cualquier otra demanda o alivio solicitados por el demandante. Usted puede perder dinero o propiendad u otros derechos importantes para usted.

USTED DEBE LLEVAR ESTE DOCUMENTO A SU ABOGADO INMEDIATAMENTE. SI USTED NO TIENE ABOGADO (O NO TIENE DINERO SUFICIENTE PARA PAGAR A UN ABOGADO) VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA NOMBRADA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASSISTENCIA LEGAL. ESTA OFICINA PUEDE PROPORCIONARLE LA INFORMACION SOBRE CONTRATAR A UN ABOGADO.
PENNSYLVANIA BAR ASSOCIATION LAWYER REFERRAL SERVICE: 1-800-692-7375
SI USTED NO TIENE DINERO SUFICIENTE PARA PAGAR A UN ABOGADO, ESTA OFICINA PUEDE PROPORCION INFORMACION COBRE AGENCIAS QUE OFRECEN SERVICIOS LEGALES A PERSONAS QUE CUMPLEN LOSE REQUISITOS PARA UN HONORARIO REDUCIDO O NINGUN HONORARIO.

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COMPLAINT

Plaintiff, the Commonwealth or Pennsylvania (the "Commonwealth") acting by and through Ryan P. Sayers, the District Attorney of Clearfield County (the "District Attorney"), brings this public enforcement action pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law. 73 P.S. §§ 201-1-201, *et seq*. ("UTPCPL" or "Statute"), against the above--named Manufacturers, Distributors, Pharmacies, and individuals with respect to their roles in the manufacturer, distribution, marketing, and sale of opioids in this Commonwealth and Clearfield County. In support of this action, the Commonwealth alleges as follows:

INTRODUCTION

1. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.[1]

2. Fueled by dangerous prescription opioid drugs, Clearfield County (the "County" or "Clearfield") — like many other counties, cities, and states across the country — is now engulfed in an opioid epidemic which has led to a public health and safety crisis of an unprecedented and disastrous nature. The current epidemic is directly attributable to the commercial activities of the Defendants and in violation of the UTPCPL.

3. The opioid crisis arose from pharmaceutical manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with pharmaceutical distributors' and dispensers' equally deliberate efforts to evade restrictions on opioid distribution and dispensing. Manufacturers, distributors, and dispensing pharmacies all acted without regard for the lives that would be impacted and/or destroyed in pursuit of their profit.

[1] Unless otherwise indicated, as used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

4. Since the Defendants push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, according to figures from the NIH National Institute on Drug Abuse and the CDC National Center for Health Statistics. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. From 1999 to 2017, almost 400,000 people died in the US from an overdose involving an opioid. In 2017, opioids were involved in 47,600 overdose deaths, which was 67.8% of all drug overdose deaths. In 2018, opioids were involved in 46,802 overdose deaths.[2] On average, about 130 Americans die every day from an opioid overdose.

5. From 1999 through 2016, overdoses killed more than 350,000 Americans. Over 200,000 of them—more than were killed in the Vietnam War—died from opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications such as OxyContin, Kadian, Actiq, Fentora, Opana, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

6. This suit takes aim at the two primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the manufacturers, distributors, and pharmacies in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

7. Prescription opioid drugs manufactured and distributed by the Defendants are

[2] Some reports suggest that these numbers are actually low because many overdose deaths fail to specify the substance involved. *See* https://www.newscientist.com/article/2235606-us-opioid-crisis-100000-overdose-deaths-may-have-gone-uncounted/ (last visited 3/10/2020).

powerful narcotic painkillers. Prescription opioids are, and at all times relevant to this action were, dangerous Schedule II and III narcotics with the potential for significant and severe adverse side effects on users, especially when taken to treat long-term pain. While they may have a proper medical use, if prescribed responsibly, to treat *short-term* acute pain (such as pain associated with medical surgical procedures, accidents or other medical conditions causing short-term pain) or for end-of-life care, Defendants marketed, promoted, sold, and distributed prescription opioids for *long-term* daily use to treat chronic pain. The overwhelming weight of medical and scientific opinion is and has been that prescription opioids should rarely be used for long-term treatment of chronic pain.

8. Beginning in the mid-1990s, the Defendants, individually and collectively, engaged in massive, systematic false and deceptive marketing aggressively promoting the prescription and use of opioids to treat chronic pain. The Defendants falsely and deceptively marketed both their own branded drugs and the entire class of opioids as safe and effective for common forms of chronic pain. Defendants' false and deceptive marketing, individually and collectively, succeeded in significantly modifying the opioid prescribing practices of physicians around the country and in Clearfield County, thereby dramatically increasing the legal prescription and use of opioids in the County, regionally, and nationally.

9. On the marketing side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioid painkillers ("Manufacturing Defendants" or "Manufacturers"). Through a massive marketing campaign premised on false and incomplete information, the Manufacturing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Manufacturing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, overstated the benefits, and trivialized the risk of the long-

term use of opioids.

10. The Manufacturing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not just for the smaller market of those suffering from severe pain associated with cancer or short-term post-operative pain, but also for much larger market of those suffering from common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were highly addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

11. Prior to the Defendants' false and deceptive marketing of opioids to doctors in the County and nationally, the medical profession considered opioids to be dangerous and to have serious adverse side effects, including addiction and increased risk of fatal and non-fatal overdoses. Medical practitioners also recognized that the risk of opioid addiction was considerable for any type of user and that opioid addiction, once it has taken hold, is impossible to cure and difficult to treat. Prior to Defendants' false and deceptive marketing, the medical profession held the view that the prescription and medical use of opioids should be cautious and limited.

12. In connection with their false and deceptive marketing, Defendants spent tens of millions of dollars promoting prescription opioids and falsely denied or trivialized their risks, while overstating the benefits of using them to treat chronic pain. As to these risks and purported benefits, Defendants falsely and deceptively: (1) downplayed the serious risk of addiction; (2) misrepresented that opioids improve patients' function and quality of life or are efficacious for chronic pain; (3) promoted the false concept of "pseudoaddiction," which posited that medical symptoms of addiction were not signs of addiction, but rather should be treated with higher and higher doses of opioids; (4) falsely claimed that opioid addiction could be easily managed; (5) falsely claimed that withdrawal symptoms could be easily addressed; and (6) denied the risks of

subjecting patients to higher opioid dosages. At the same time, Defendants touted the ostensible benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientific evidence to support these claims.

13. Defendants' false and deceptive marketing practices were specifically designed to reverse both the popular and medical understanding that opioids were not appropriate to treat chronic pain. Defendants disseminated their promotional messages directly to physicians through their massive sales efforts involving sales calls by armies of sales representatives (referred to as "detailing"), the dissemination of written marketing materials, and through speaker groups led by physicians whom Defendants paid to support their marketing messages.

14. Defendants also worked through third parties that they controlled by: (1) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (2) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups ("Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint sources that doctors and patients relied on for ostensibly "neutral" independent medical guidance, such as treatment guidelines, continuing medical education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known to be true – that opioids were highly addictive drugs, unsafe in most circumstances for long-term use – was actually untrue, and quite the opposite, that the compassionate treatment of pain *required* prescription opioids.

15. Contrary to Defendants' marketing, after a comprehensive review of the increased use of prescription opioids for medical purposes and its ill effects during the last 20 years, public health authorities and medical researchers have now reaffirmed and acknowledged that there never was satisfactory scientific evidence to establish that they were effective in treating chronic pain.

16. They also have concluded that long-term daily use of prescription opioids was unsafe and exposed patients to dangerous, unacceptable risks of addiction, fatal and non-fatal overdoses, and other serious adverse health conditions and that such risks significantly and dangerously increased with the increased use of prescription opioids. In this light, Defendants' activities in aggressively marketing, promoting, distributing, dispensing, and selling prescription opioids as a safe and effective treatment for chronic pain were medically and scientifically unfounded, false, deceptive, ethically inexcusable, and unlawful.

17. On the supply side, the crisis was fueled and sustained by those involved in the distribution and dispensing of opioids, including manufacturers, distributors, and pharmacies who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. These Defendants have contributed substantially to the opioid crisis by distributing and dispensing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt, suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market. These entities themselves, not their individual employees, had a common law duty to put policies in place at a corporate level for monitoring, reporting, and halting suspicious orders and purchases, yet they failed to do so, causing significant harm in this County.

18. At the same time, the Defendants in control of the supply chain falsely and deceptively claimed that, among other things, they had sufficient and effective policies and procedures in place for monitoring, reporting, and halting suspicious orders; that they had policies and procedures in place to detect and prevent diversion; that they were actively cooperating with law enforcement to monitor, report, and prevent diversion; that they had prioritized the safety and well-being of their customers over their profits; and that they were engaged in efforts to prevent

and treat addiction.

19. Certainly, as millions of people became addicted to opioids, "pill mills," self-styled as "pain clinics," sprouted nationwide and in this Commonwealth, while rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issued high volumes of opioid prescriptions under the guise of medical treatment. However, prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without the negligence, willful blindness, or knowing support of those in the supply chain.

20. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Clearfield County, are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis." The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin, fentanyl, and methamphetamine abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

21. Thus, rather than compassionately helping patients in pain, this explosion in opioid use—and Defendants' enrichment—has come at the expense of patients and Plaintiff and has caused ongoing harm and damages to Plaintiff. As the CDC director concluded in 2014: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

22. Most of the overdoses from non-prescription opioids are also directly related to the flood of prescription pills unleashed by Defendants. Many opioid users, having become addicted to but no longer able to obtain or afford prescription opioids, have turned to heroin, fentanyl, methamphetamine or other illicit drugs. According to the National Institute on Drug Abuse, 80%

of people who initiated heroin use in the past decade started with prescription opioids.[3] In fact, people who are addicted to prescription opioids are 40 times more likely than people not addicted to prescription opioids to become addicted to heroin, and the CDC has identified addiction to prescription opioids as the strongest risk factor for heroin addiction.[4]

23. Clearly, but tragically, the Defendants' push to increase opioid sales has worked. Defendants false and deceptive marketing, coupled with their failure to monitor the supply chain and prevent diversion, dramatically increased their sales of prescription opioids and allowed them to reap billions of dollars of profit. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

24. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion.

25. The opioid epidemic currently plaguing the County and its deleterious impact on public health and safety have created overlapping crises for the County, its residents, and the community as a whole. This has adversely affected public and private health plans and third-party payors of prescription drug benefits of these health plans, as well and the County and its agencies, including the District Attorney's office. These adverse impacts include, but are not limited to:

a. Opioid addiction and the adverse health consequences of prescription opioid use, which have exacted a grim toll of human suffering on users and their families. As a consequence, the legal purchase and use of prescription opioids have placed an enormous burden on public and private health plans in the County and on third-party payors

[3] https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use
[4] https://www.cdc.gov/vitalsigns/heroin/index.html

of prescription drug benefits of these plans to defray the costs of the prescriptions and treatment of the adverse side effects of prescription opioids; and

b. The opioid crisis and its attendant increase in crime and family and social dysfunction which tear at the social fabric of the County. This has caused a sharp deterioration of public safety, order, economic productivity, and the quality of life in the County. As a consequence, the County and its agencies, including the District Attorney, which are in the front lines of attempting to cope with and contain the epidemic and the adverse impacts on public health and safety, have incurred large, burdensome, unnecessary, and avoidable costs in the discharge of their duties.

26. Defendants' false and deceptive conduct, which has precipitated and perpetuated the opioid epidemic in the County, violated and continues to violate the UTPCPL.

27. The District Attorney of Clearfield County, in the name of the Commonwealth, brings this action to hold Defendants accountable under the UTPCPL for their role in creating and perpetuating the opioid crisis in the County; seeks injunctive relief against the Defendants; fines of not less than $1,000 for each instance of the Defendants' false or misleading statements made or disseminated within the County; and, through the restoration and/or restitution provision in the Statute, disgorgement of the revenues acquired by the Defendants as a result of their violations of the Statute and compensation for the losses of the County, the District Attorney, and other affected persons in interest within the County attributable to those violations, including, *inter alia*, the addiction treatment and prescriber education necessary to abate the epidemic.

28. To redress and punish Defendants' violations of the UTPCPL, the Commonwealth also seeks an order from the Court enjoining Defendants from further false and deceptive marketing activities in the County regarding the use of prescription opioids for chronic pain and/or ordering Defendants to inform the medical community and the public of the true risks of long-term

opioid prescription opioid use.

29. The Commonwealth also specifically seeks restoration and/or restitution from Defendants to the County and other injured persons in interest in or doing business therein, including any health plans, third-party payors or administrators of prescription drug benefits who paid opioid-related claims, of the monies paid for purchases of opioid prescriptions, treatment of opioid addiction or abuse or related diseases attributable to prescription opioids, and other costs and damages that Defendants' violations of the law caused and contributed to.

30. The Commonwealth also seeks restoration and/or restitution relief requiring Defendants to pay to the County and the District Attorney for its expenditures for (1) increased County services associated with addiction, fatal and non-fatal overdoses and other adverse health and public safety conditions attributable to prescription opioids manufactured, distributed, and dispenses by Defendants, including the increased emergency response costs, hospitalization, treatment, and other costs; (2) any other monies lost or expenses incurred by the County and the District Attorney as a result of Defendants' violations of the UTPCPL and (3) all additional legal or equitable relief authorized by law.

JURISDICTION AND VENUE

31. This Court has jurisdiction over this action pursuant to 42 Pa. C.S. § 931(a). The amount in controversy exceeds $50,000, exclusive of interest and costs, which is the jurisdictional amount below which a compulsory arbitration referral pursuant to 42 Pa. C.S. § 7361(b) would be required.

32. Venue is proper in Clearfield County pursuant to 42 Pa. C. S. § 931(c), Pa. R.C.P. 1006(a); 1006(b) and (c)(1), and Pa. R.C.P. 2179(a).

33. This action is not removable to federal court. Among other things, there is insufficient diversity for removal. The Commonwealth is not considered a party for purposes of

diversity of citizenship jurisdiction in any event. Further, the claims alleged in the Complaint do not permit federal question jurisdiction to be exercised as the claims do not arise directly or indirectly under the Constitution, laws, or treaties of the United States. Nor is this matter removable as a class action, since it is not brought pursuant to a state statute or rule that is similar to F.R.C.P. 23.

PARTIES

I. PLAINTIFF

34. Plaintiff is the Commonwealth of Pennsylvania, acting by and through the District Attorney of Clearfield County, pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1 – 201-9.3.

35. The District Attorney is expressly authorized to bring this action in the name of the Commonwealth under the UTPCPL whenever the District Attorney has reason to believe that any person is using or is about to use any method, act or practice declared by the UTPCPL to be unlawful, and that such proceedings would be in the public interest. 73 P.S. § 201-4.

36. Based on the allegations herein, the District Attorney has reason to believe that Defendants are using or are about to use methods, acts or practices declared by the UTPCPL to be unlawful and that bringing this action is in the public interest.

II. DEFENDANTS

A. The Manufacturer Defendants

37. At all relevant times, Manufacturer Defendants have manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. In addition, the

Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

1. Purdue

38. Defendant Purdue Pharma L.P. ("PPL") is a privately held limited partnership organized under the laws of Delaware, with its principal place of business in Stamford, Connecticut.

39. Defendant Purdue Pharma Inc. ("PPI") is a privately held New York corporation, with its principal place of business in Stamford, Connecticut.

40. Defendant The Purdue Frederick Company, Inc. ("PFC") is a privately held New York corporation, with its principal place of business in Stamford, Connecticut.

41. Defendant Rhodes Technologies ("Rhodes Tech") is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, R.I.

42. Defendant Rhodes Technologies Inc. ("Rhodes Tech Inc.") is a Delaware corporation formed January 28, 1999 with its principal place of business in Coventry, R.I. Rhodes Tech Inc. is a general partner of Rhodes Tech.

43. Defendant Rhodes Pharmaceuticals L.P. ("Rhodes Pharma") is a Delaware limited partnership formed November 9, 2007 with its principal place of business in Coventry, R.I.

44. Defendant Rhodes Pharmaceuticals Inc. ("Rhodes Pharma Inc.") is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma.

45. Defendant The P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business located in Totowa, New Jersey.

46. PPLP, PPI, PFC, Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., and PF Labs are collectively referred to herein as "Purdue."

47. At all times material hereto, Purdue promoted, marketed, and sold opioids nationally and in Clearfield County, including but not limited to the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

48. More than half of Purdue's revenue came from opioids.[5]

49. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

50. At all relevant times, Purdue has been beneficially owned, managed, and controlled by the families of Mortimer Sackler and Raymond Sackler, both of whom are now deceased.

51. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990's, served as a member of the board of directors of Purdue and Purdue-related entities.

52. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is a son of Raymond Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

[5] Esme Deprez, The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry, Bloomberg Businessweek (Oct. 5, 2017), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

53. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

54. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

55. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

56. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

57. Defendant Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

58. Defendant David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

59. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust") is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

60. Defendant Stuart D. Baker is a natural person residing in Suffolk County, New

York. He has served as a senior executive of, and/or counsel to, Purdue, Purdue-related entities, and members of the Sackler families since the 1990s.

61. Purdue and its top executives pleaded guilty in 2007 to criminal charges in connection with Purdue's deceptive OxyContin marketing practices, as discussed herein.

62. Purdue made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

63. Each of Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Raymond Sackler Trust (through its trustees), and Stuart D. Baker (collectively "Purdue-Related Additional Defendants") knowingly directed, aided, abetted, participated in, and benefitted from the wrongdoing of Purdue alleged herein.

2 Actavis/Allergan

64. Upon information and belief, Defendants Actavis and Allergan are an interconnected group of companies that manufacture opioids. They have repeatedly formed, reformed, and changed their corporate structures and entities, which has significantly concealed the roles and relationships of individuals, officers, and corporations within and among this group.

65. Defendant Allergan Finance, LLC is a privately held Nevada corporation with its principal place of business in Parsippany, New Jersey. Defendant Allergan Finance, LLC was formerly known as Actavis, Inc., which in turn was formerly known as Watson Pharmaceuticals, Inc. Defendant Allergan Finance, LLC acquired Warner Chilcott plc in 2013. Defendant Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc, which is incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan Finance, LLC and Allergan plc are

collectively referred to as "Allergan."

66. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

67. Defendant Actavis Pharma, Inc. is registered to do business with the Ohio Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

68. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

69. Each of these defendants and entities is owned or has been owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States.

70. Each of these entities is liable for the conduct of the other under the alter ego principle in that the relationships demonstrate invasive control by the parent corporation over its subsidiary and disregard for traditional corporate boundaries. They may also be held accountable on the basis of successor liability.

71. Defendant Allergan plc, Allergan Finance, LLC, Actavis, and their predecessors and/or combined entities, including but not limited to Actavis, Inc., Watson Pharmaceuticals, Inc., and Warner Chilcott plc (collectively referred to herein as "Allergan/Actavis") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Clearfield County, including but not limited to the following:

Table 2. Allergan/Actavis Opioids

Drug Name	Chemical Name	Schedule
Kadian	Morphine sulfate extended release	Schedule II
Norco	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic Duragesic	Fentanyl	Schedule II

Generic Kadian	Morphine sulfate extended release	Schedule II
Generic Opana	Oxymorphone hydrochloride	Schedule II

2. Teva/Cephalon

72. Upon information and belief, Defendants Teva and Cephalon are an interconnected group of companies that manufacture opioids. They have repeatedly formed, reformed, and changed their corporate structures and entities, which has significantly concealed the roles and relationships of individuals, officers, and corporations within and among this group.

73. Defendant Teva Pharmaceuticals USA, Inc. is a privately held Delaware corporation, with its principal place of business in North Wales, Pennsylvania. Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Defendant Teva Pharmaceuticals USA, Inc. specializes in the manufacturing and marketing of generic drugs, including opioids.

74. Defendant Cephalon, Inc. is a privately held Delaware corporation with its principal place of business in North Wales, Pennsylvania. In 2011, Cephalon, Inc. was acquired by Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Cephalon, Inc. is now a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

75. At all times material hereto, Defendants Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively, "Teva") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Clearfield County, including but not limited to the following:

Table 3. Teva Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II
Generic oxycodone	Oxycodone hydrochloride	Schedule II

3. Endo

76. Defendant Endo Health Solutions Inc. ("Endo Health") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health is a wholly owned subsidiary of Endo International plc, which is an Ireland-domiciled company.

77. Defendant Endo Pharmaceuticals, Inc. ("Endo Pharmaceuticals") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals is a wholly owned subsidiary of Defendant Endo Health.

78. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Defendant Par Pharmaceutical Companies, Inc., a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively herein as "Par Pharmaceutical."

79. At all times material hereto, Defendants Endo Health, Endo Pharmaceuticals, Par Pharmaceutical (collectively, "Endo") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Clearfield County, including but not limited to the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Zydone	Hydrocodone bitartrate and acetaminophen	Schedule III
Generic Oxycodone	Oxycodone hydrochloride	Schedule II
Generic Oxymorphone	Oxymorphone hydrochloride	Schedule II
Generic Hydromorphone	Hydromorphone hydrochloride	Schedule II
Generic Hydrocodone	Hydrocodone	Schedule II

80. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15 billion

from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

81. In 2017, Endo Pharmaceuticals removed Opana ER from the market due to serious risks of abuse.[6]

4. Janssen/J&J

82. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation, with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals is a wholly owned subsidiary of Defendant Johnson & Johnson. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceuticals, Inc.

83. Defendant Johnson & Johnson ("J&J") is a publicly traded New Jersey corporation, with its principal place of business in New Brunswick, New Jersey. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, and Janssen Pharmaceuticals' profits inure to J&J's benefit.

84. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

85. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

86. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as

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[6] *See* Opana Form 10-Q for the quarter ended June 30, 2017, 22, http://www.endo.com/investors/sec-filings.

Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

87. At all times material hereto, Defendants Janssen Pharmaceuticals, J&J, Noramco, OMP, and Janssen Pharmaceutica (collectively, "Janssen") manufactured, promoted, marketed, and sold opioids nationally and in Clearfield County, including but not limited to the following:

Table 5. Janssen/J&J Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta	Tapentadol	Schedule II
Nucynta ER	Tapentadol extended release	Schedule II
Ultram	Tramadol hydrochloride	Schedule IV

88. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

89. J&J is also one of the world's largest legal poppy growers. Through its subsidiary, Tasmanian Alkaloids, J&J supplies precursor opium for much of the hydrocodone and oxycodone consumed in the United States.

90. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

91. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

92. J&J controls the sale and development of Janssen's drugs, J&J handles Jansen's dealings with the FDA concerning Janssen's drugs, and Janssen's profits inure to J&J's benefit.

5. Mallinckrodt

93. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June 2013. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

94. Defendant Mallinckrodt LLC is a Delaware corporation with its principal place of business in Hazelwood, Missouri.

95. Defendant SpecGx LLC is a Delaware limited liability company with its principal place of business in Clayton, Missouri and a wholly owned subsidiary of Mallinckrodt plc.

96. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "Mallinckrodt") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States and in Clearfield County.

97. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the

top ten generic pharmaceutical manufacturers in the United States based on prescriptions.

98. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, and Roxicodone, which is oxycodone. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

99. Mallinckrodt has also been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

100. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

101. Among the drugs Mallinckrodt manufactures or has manufactured and distributed nationally and in Plaintiff's Community are the following:

Table 6. Mallinckrodt Opioids

Product Name	**Chemical Name**	**Schedule**
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II

Product Name	Chemical Name	Schedule
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic	Hydromorphone hydrochloride	Schedule II
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	unscheduled
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II
Generic	Buprenorphine and naloxone	Schedule III

102. Purdue (including the Sacklers and Stuart Baker), Allergan/Actavis, Teva, Endo, Janssen/J&J, and Mallinckrodt are collectively referred to herein as the "Manufacturer Defendants."

103. Each of these Defendants has made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating on speakers bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

B. The Distributor Defendants

104. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to monitor, report, and halt the diversion of dangerous drugs for non-medical purposes. As such, the Distributor Defendants universally failed to comply with their legal duties. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the excessive volume of prescription opioids plaguing Plaintiff's Community and of the diversion of prescription opioids into Plaintiff's Community.

1. AmerisourceBergen

105. Defendant AmerisourceBergen Drug Corp. ("AmerisourceBergen") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania.

106. Through its various subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Clearfield County. AmerisourceBergen is the twelfth largest company by revenue in the United States, with annual revenue of more than $153 billion in 2017.

107. AmerisourceBergen has been licensed as a wholesale distributor of dangerous drugs in Pennsylvania since 1988.

2. Cardinal

108. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

109. Cardinal describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the United States with $130 billion in revenue in 2017, a 7% increase over the previous year.

110. Cardinal distributes opioids and other pharmaceutical drugs throughout the United

States, including in Clearfield County.

3. McKesson

111. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

112. It is the largest pharmaceutical distributor in the United States and the sixth largest company by revenue, with $198.5 billion in revenue in 2017. McKesson is a wholesale distributor of pharmaceutical drugs, including opioids, throughout the country, including Clearfield County.

113. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [DEA] registered distributor."

4. Anda

114. Defendant Anda, Inc. ("Anda"), is a Florida corporation with its principal office located in Olive Branch, Mississippi.

115. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva USA acquired Anda for $500 million in cash.

116. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Pennsylvania and Clearfield County.

5. H.D. Smith

117. Defendant H.D. Smith Wholesale Drug Company ("H.D. Smith") is a Delaware corporation with its principal place of business in Springfield, Illinois.

118. H.D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to this Complaint, H.D. Smith distributed prescription opioids throughout the United States, including in Pennsylvania and Plaintiff's Community.

6. Walmart

119. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. ("Wal Mart"), is a Delaware corporation with its principal place of business in Arkansas. Wal-Mart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor and pharmacy. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids and engaged in retail selling of opioids throughout the United States, including in Pennsylvania and Plaintiff's Community.

7. CVS

120. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island. Together CVS Health Corporation, CVS Pharmacy Inc., CVS Indiana LLC, CVS Rx Services, Inc, CVS TN Distribution, LLC, CVS of Pennsylvania, Inc., CVS PA Distribution, L.L.C. are collectively referred to as "CVS."

121. Through its various DEA registered subsidiaries and affiliated entities, CVS conducts business as a licensed wholesale distributor and pharmacy. It also operates retail stores which sell prescription medicines including opioids.

122. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Pennsylvania and Plaintiff's Community.

8. Rite Aid

123. Defendant Rite Aid Corporation is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc., is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

124. Together, Rite Aid Corporation, Rite Aid of Maryland, Inc., Rite Aid Drug Palace Inc, Rite Aid of Pennsylvania, Inc, and Rite Aid of Pennsylvania, LLC are referred to as "Rite Aid."

125. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, which sell prescription medicines, including opioids.

126. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Pennsylvania and Plaintiff's Community.

9. Giant Eagle

127. Defendant Giant Eagle, Inc. is registered to do business in Pennsylvania with its headquarters located in Pittsburgh. Its annual revenue is over 6 billion dollars. Giant Eagle Drugs is also registered to do business in Pennsylvania with an address in Pittsburgh.

128. Defendant Giant Eagle, Inc and Giant Eagle Drugs, are collectively referred to as "Giant Eagle."

129. Giant Eagle owns and operates supermarkets in Pennsylvania, Ohio, West Virginia, Indiana, and Maryland, including in Clearfield County.

130. Giant Eagle, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Giant Eagle also operates retail pharmacies

within its supermarkets, which sell prescription medicines, including opioids.

131. At all times relevant to this Complaint, Giant Eagle, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Pennsylvania and Plaintiff's Community.

10. Giant/Martin's

132. The Giant Company LLC is registered to do business in Pennsylvania with its headquarters located in Carlisle. Ahold USA, Inc. is likewise registered to do business in Pennsylvania with its headquarters, upon information and belief, in Carlisle. These two entities are referred to collectively as "Giant/Martin's."

133. Giant/Martin's operates Giant and Martin's supermarkets in Maryland, Virginia, West Virginia, and western Pennsylvania, including Clearfield County. These are owned by Ahold USA, Inc.

134. Giant/Martin's, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Giant/Martin's also operates retail pharmacies within its supermarkets, which sell prescription medicines, including opioids.

135. At all times relevant to this Complaint, Giant/Martin's, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Pennsylvania and Plaintiff's Community.

11. Value Drug Company

136. Value Drug Company ("Value Drug") is registered to do business in Pennsylvania with its headquarters located at 195 Theater Drive, Duncansville, Pennsylvania.

137. Upon information and belief, Value Drug Company is an independent wholesale distributor of brand, generic, and specialty pharmaceuticals.

138. Value Drug operates as a purchasing cooperative for hundreds of independent pharmacies and provides whole distribution of pharmaceuticals, including opioids, to its member pharmacies.

139. The President of Value Drug is Greg Drew, a former Rite Aid executive.

140. The stated mission of Value Drug is to faciliate "optimum patient care in the community and long term care environments." It holds itself out as a wholesaler that can help pharmacies "meet the challenges facing independent pharmacy and provide innovative, valuable programs and services to increase your pharmacy's growth and prosperity." It also claims to be a partner for pharmacies that understands the regulatory issues surrounding the distribution and dispensing of pharmaceuticals.[7]

141. According to the federal ARCOS database, between 2006 and 2014 Value Drug controlled 38.80% of the market for the distribution of opioids in Clearfield County, distributing over 13 million dosage unites.

142. AmerisourceBergen, Cardinal, McKesson, Anda, H.D. Smith, Walmart, CVS, Rite Aid, Giant Eagle, Giant/Martin's, and Value Drug are referred to collectively herein as the "Distributor Defendants."

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[7] *See* Value Drug Company LinkedIn profile, "About" section, https://www.linkedin.com/company/value-drug-company/about/ (last visited August 6, 2020) ("As competition increases and network access decreases, as reimbursements shrink and regulations expand, you need more than just a wholesaler—you need a partner. At Value Drug, we understand the regulatory issues and marketplace challenges that independent pharmacists must contend with each day. We've assembled a diverse portfolio of programs and services that

C. The Pharmacy Defendants

143. All of the Pharmacy Defendants are both Distributors and Retailers of prescription opioids. These Defendants have or continue to distribute opioids to their own pharmacies within Clearfield County. At the same time, they own and operate pharmacies within Clearfield County that dispense prescription opioids, either obtained from their own distribution arm of from another of the Distributor Defendants.

144. The Pharmacy Defendants have violated their statutory and common law duties as both distributors and retailers of prescription opioids.

145. At all relevant times, the Pharmacy Defendants have dispensed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their duty to detect and warn of diversion of dangerous drugs for non-medical purposes. As a retailer of highly addictive drugs, Pharmacy Defendants have a duty to act with reasonable care in the sale of these drugs within Clearfield County. The Pharmacy Defendants universally failed to comply with their legal duties. Instead, they dispensed opioids in quantities that could not have been expected to serve legitimate medical use and ignored other red flags and suspicious orders.

146. At the same time, the Pharmacy Defendants have misrepresented their compliance with their legal duties and/or made false and misleading statements about their efforts to monitor suspicious orders, prevent diversion, and combat addiction.

147. Walmart, CVS, Rite Aid, Giant Eagle, and Giant/Martin's are referred to collectively as the "Pharmacy Defendants."

D. Agency and Authority

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satisfy both the customer's need for convenience and low-cost healthcare and the pharmacist's need to increase growth, efficiency and profitability.").

148. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees or other representatives while actively engaged in the management of Defendants' affairs within the course and cope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

E. Affiliates of Named Defendants

149. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

150. These entities may also be held liable on the basis of successor liability or under the alter-ego theory.

GENERAL ALLEGATIONS

I. PRESCRIPTION OPIOIDS AND THEIR ADVERSE HEALTH EFFECTS

151. Most prescription opioids are natural and semi-synthetic drugs derived from the active ingredients of opium. Prescription opioids include the drug formulations identified herein. The most commonly prescribed are formulations (both branded and generic) of hydrocodone, oxycodone, oxymorphone and hydromorphone.[8]

152. Opium and opium derivatives including prescription opioids have both pain relieving and euphoria-inducing characteristics. The pain-relieving properties of opium have been recognized for millennia. During and after the Civil War, opioids, sometimes known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, and they were popularly used in a wide variety of commercial products ranging

[8] Fentanyl is also a prescription opioid and the subject of deceptive marketing and misuse. Fentanyl is a wholly synthetic prescription opioid that is similar to morphine, but is 50 to 100 times more potent. *See* https://www.drugabuse.gov/drugs-abuse/fentanyl.

from pain elixirs to cough suppressants to beverages.

153. Unfortunately, prescription opioids pose the same dangers and hazardous side effects associated with opium and opium derivatives such as morphine and heroin, and have a high degree of potential for abuse and addiction. Opium (or the active ingredients thereof) is the foundational component of heroin and prescription opioids, and both types of drugs function in an essentially identical fashion.

154. Prescription opioids work by binding to receptors on the spinal cord and in the brain, altering the perception of pain. Opioid addiction is a medical disease that arises from repeated exposure to opioids. It can occur in individuals using prescription opioids to relieve pain under the supervision of a physician at prescribed doses, just as it can occur in individuals using opioids for non-medical purposes.

155. Discontinuing opioid use even after just a few days of therapy can cause patients to experience withdrawal symptoms. The odds that an individual will still be on opioids a year after starting a short course begin to increase after only 5 days. Withdrawal symptoms can include anxiety, nausea, vomiting, agitation, insomnia, muscle aches, abdominal cramping, and other serious conditions, which may persist for months or longer after a complete withdrawal from opioids, depending on how long the opioids were used.[9]

156. When opioids are used over time, patients grow tolerant to their analgesic and euphoric effects. As tolerance increases, a patient requires progressively higher doses in order to obtain the same levels of pain reduction to which he or she has become accustomed.[10] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at an even higher risk

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[9] *See, e.g.*, Health Guide: Opiate Withdrawal, The New York Times (2013), http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

[10] M. Katz, Long-Term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

of addiction.[11]

157. Opioids can cause severe respiratory depression (meaning that breathing slows to the point that the body cannot adequately exhale carbon dioxide), coma, and/or death. These serious hazards can occur even when used at prescribed doses and can affect – sometimes fatally – even users who are not suffering from opioid addiction or opioid use disorder.

158. Up to the mid-1990s, the medical profession viewed opioids as having legitimate uses, but believed that they should be prescribed cautiously and only on a limited basis because of concerns about addiction, tolerance leading to dose escalation, and physiological dependence resulting in difficulty discontinuing use. Physicians were reluctant to prescribe opioids on a long-term basis for common chronic pain conditions because of their addiction risks and side effects.[12]

159. In the late 1990s, however, the rate of prescription opioid use, particularly for the treatment of chronic pain, began accelerating rapidly. In the early 1990s, the number of opioid prescriptions at U.S. pharmacies increased by two to three million each year. From 1995 to 1996, the number of prescriptions jumped by eight million. This acceleration was directly related to and was caused by efforts of the Manufacturer Defendants to falsely and deceptively promote the benefits of long-term prescription opioid use and minimize their risks in order to take advantage of the lucrative market for chronic pain patients. The Manufacturer Defendants' efforts in this regard are alleged more fully below.

160. The crisis is also the result of the Distributor and Pharmacy Defendants' failure to

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[11] In a study conducted by Kidner and colleagues, they found that higher doses of opioids (greater than 61 mg/day of morphine equivalents) predicted worse outcomes, including program non-completion, lower rates of return to work, and higher health care utilization. Furthermore, studies have shown that the prevalence of mental health diagnoses increases with increasing duration of opioid use. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3641146/.

[12] Andrew Kolodny *et al.*, The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 562 (Jan. 12, 2015) (hereinafter "Kolodny, Jan. 12, 2015"), https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

effectively control the supply of prescription opioids, which they knew to be dangerous and highly addictive.

161. The Distributor and Pharmacy Defendants failed to identify and report suspicious orders of opioids to the appropriate regulatory agencies, as required by law. Instead, they filled those orders, substantially contributing to the opioid crisis.

162. The Distributor and Pharmacy Defendants distributed and sold opioids in far greater quantities than they knew to be necessary for legitimate medical uses, fueling a vast illegal secondary market that has contributed to the current opioid-related crisis in Clearfield County. Illegal opioid sales were channeled through "pill mills," which often presented as "pain clinics" with licensed medical professionals selling high volumes of prescription opioids illegally. The Distributor Defendants refused to comply with their licensing requirements and stop suspicious orders of opioid pills, which facilitated an almost limitless supply of opioid pills to the increasing number of people suffering from opioid addiction.

163. The Pharmacy Defendants failed in their duty to put policies in place that would have identified and mitigated this diversion.

164. On the contrary, the Distributors and Pharmacies misrepresented their compliance with their duties and also falsely and/or misleadingly claimed that they were making efforts to combat diversion, addiction, and the opioid epidemic.

165. All three groups- Manufacturers, Distributors, and Pharmacies- chose to maximize their profits instead of complying with their common law and statutory duties, which had the foreseeable consequence of fueling the deadly opioid epidemic that is currently wreaking havoc on the Country, Pennsylvania, and Clearfield County.

166. Scientific evidence has not demonstrated the safety or efficacy of prescription opioids for long-term daily use to treat chronic pain.[13]

167. As a result of widespread, scientifically unsupported use of prescription opioids for long-term chronic pain, the U.S. Centers for Disease Control and Prevention ("CDC") developed the "CDC Guideline for Prescribing Opioids for Chronic Pain" in March 2016 (the "2016 CDC Guideline").[14] The 2016 CDC Guideline extensively discussed the lack of evidence supporting opioid use to treat chronic pain.

168. Chronic pain generally refers to pain lasting three months or longer. In the 2016 CDC Guideline, the CDC stated: "Chronic pain has been variably defined but is defined within this [opioid treatment] guideline as pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause."[15]

169. As indicated by the CDC, there are no controlled studies of the use of opioids to treat chronic pain beyond 12 weeks, and no reliable evidence that opioids improve patients' pain and function long-term.[16]

170. Based on a detailed review of prior opioid studies, the CDC concluded that "evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited,

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[13] The National Institutes of Health and the Agency for Healthcare Research and Quality issued a report that found no evidence for effectiveness of long-term opioid use for chronic pain, but a disquieting amount of evidence for harm, including overdoses and addiction. *See* https://www.painresearchforum.org/news/46387-long-term-opioid-therapy-chronic-pain-more-harm-good.

[14] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, The Center for Disease Control and Prevention, (March 18, 2016) (hereinafter "*CDC Guideline*, March 18, 2016"), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[15] *Id.* at pg. 1.

[16] *Id.* at pg. 2, 9.

with insufficient evidence to determine long-term benefits versus no opioid therapy."[17] The CDC further stated: "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . . ."[18] The 2016 CDC Guideline also stated: "Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)."[19] A study by the New England Journal of Medicine concluded that the risks of extended prescriptions of opioids for the treatment of chronic pain, the risk of overdose and addiction increase with higher doses, longer duration of prescribing, and perhaps the use of long-acting opioids. Despite these facts, a Medicaid study showed that more than 50% of opioids prescriptions were for doses higher than 90 morphine milligram equivalents (MME) and for periods of more than 6 months.[20]

171. As referred to in the 2016 CDC Guideline, the first randomized, placebo controlled studies appeared in the 1990s, and revealed evidence only for *short-term* efficacy of opioids, and only in a minority of patients.[21] Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently noted the lack of available data to assess long-term outcomes.

172. On the other hand, substantial evidence exists indicating that opioid drugs are *ineffective* to treat chronic pain, and actually *worsen* patients' health. While opioids may work to control pain in short-term applications, long-term use very often leads to a decline in the patient's overall functionality, general health, mental health, and social function. A study conducted by the U.S. Department of Health and Human Services concluded that higher doses of opioids are

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17 *Id.* at pg. 9 (emphasis added).
18 *Id.* at pg. 15.
19 *Id.* at pg. 15.
20 Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies, N. Engl. J. Med. 2016, https://www.nejm.org/doi/full/10.1056/NEJMra1507771.
21 Nathaniel Katz, Opioids: After Thousands of Years, Still Getting to Know You, 23(4) Clin. J. Pain 03 (2007); Roger Chou *et al.*, Research Gaps on Use of Opioids for Chronic Noncancer Pain, 10(2) J. Pain 147 (2009).

associated with a greater risk of physical dependence, fractures, heart problems and endocrine effects.[22]

173. Studies have shown that increasing the duration of opioid use is strongly associated with an increasing prevalence of negative mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater utilization of health care services. Over time, even high doses of opioids often fail to control pain due to tolerance levels rising, and many patients exposed to such doses are unable to function normally. Of people taking opioids for a year, as many as 8% ended up misusing or addicted to their medications while as many as 26% became physically dependent upon them.[23]

174. A 2007 systematic review of opioids for back pain found that the evidence did not allow judgments regarding long-term use.[24]

175. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy was "poor."[25]

176. What is more, there is even evidence that the Defendants opioids are not even effective at treating their original and intended target: cancer pain.[26]

177. As a result of wide acknowledgment that opioids are neither safe nor effective for

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[22] The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, No. 218, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-opioid-treatment_research.pdf.

[23] *See, supra* n. 12; https://www.painresearchforum.org/news/46387-long-term-opioid-therapy-chronic-pain-more-harm-good.

[24] BA Martell, *et al.*, Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction, Annals of Internal Medicine (2007), https://www.ncbi.nlm.nih.gov/pubmed/17227935.

[25] L. Manchikanti, *et al.*, A Systematic Review of Randomized Trials of Long-Term Opioid Management for Chronic Non-Cancer Pain, Pain Physician (2011), https://www.ncbi.nlm.nih.gov/pubmed/21412367.

[26] D. Koyyalagunta, *et al.*, A Systematic Review of Randomized Trials on the Effectiveness of Opioids for Cancer Pain, Pain Physician (2012), https://www.ncbi.nlm.nih.gov/pubmed/22786461.

long-term use, in February 2017 the "Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain" strongly recommended "against initiation of long-term opioid therapy for chronic pain."[27]

II. THE MANUFACTURER DEFENDANTS' FALSE AND DECEPTIVE CONDUCT IN MARKETING OPIOIDS

178. The Manufacturer Defendants improperly marketed opioids for years, using false and deceptive marketing that overstated and/or misrepresented the safety and efficacy of opioids and understated the risks of those drugs.

179. The Manufacturer Defendants' false and deceptive marketing was effective in convincing prescribers, pharmacists, patients, third-party payors, pharmacy benefit managers, health plan administrators, and others responsible for selecting and approving prescription drugs (including opioids) covered by health insurance plans, that prescription opioids could be safely used on a long-term basis to treat chronic pain, that prescription opioids were an effective treatment for chronic pain, and that the benefits of using opioids to treat chronic pain far outweighed the risks.

180. The Manufacturer Defendants' marketing specifically targeted prescribers, pharmacists, and patients, as well as the individuals and groups responsible for selecting opioid drugs covered by health coverage plans and included on pharmacy formularies (*i.e.*, insurers, pharmacy benefit managers, and others).

181. The Manufacturer Defendants, however, knew that these marketing and product promotion claims were false, misleading, deceptive and likely to misinform or confuse the targets of the marketing and product promotion described above. Among other things, and as more fully

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[27] Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Department of Defense, Department of Veteran's Affairs, V:3, 7 (2017), https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf.

set forth herein, the Manufacturer Defendants knew that controlled studies of the safety and efficacy of prescription opioids were limited to short-term use in monitored settings (*e.g.*, hospitals) where the risks of addiction, abuse, overdose, and other adverse outcomes were minimized, and that long-term studies demonstrating the safety and efficacy of prescription opioids for long-term use did not exist.

182. The Manufacturer Defendants also knew or disregarded the fact that the effectiveness of prescription opioids wanes with prolonged use, requiring increases in dosage to achieve ongoing pain relief, which markedly increases the risk of significant side effects, addiction, and overdose when used for long-term treatment.

183. Despite these facts – well known to Defendants for many years – the Manufacturer Defendants sought to create a false perception of the safety and efficacy of prescription opioids for long-term daily use to treat chronic pain, including to treat a wide range of conditions including such common ones as lower back pain, arthritis, and headaches.

184. The Manufacturer Defendants engaged in this false and deceptive conduct because they recognized that chronic pain patients could provide a much larger, and far more lucrative, market for prescription opioids than patients with acute pain or cancer pain at the end of life. It is estimated that chronic pain affects one in five Americans and will afflict even more as the incidence of diseases such as diabetes, obesity, and arthritis rises in the aging population.[28] To take advantage of this potentially massive market, the Manufacturer Defendants engaged in these false and deceptive marketing activities to promote prescription opioids for the management of chronic pain, thereby consciously and unconscionably elevating corporate profits above the interest and well-being of patients.

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[28] James Dahlamer, *et al.*, Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults- United States, 2016, The Center for Disease Control (Sept. 14, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm?s_cid=mm6736a2_w.

185. The Manufacturer Defendants created a falsely favorable perception of prescription opioids through coordinated, sophisticated, and highly deceptive marketing that began in the mid-1990s and continues to the present.

186. In 1996, opioid sales and use began accelerating rapidly. This acceleration was triggered initially by the introduction in 1995 of Defendant Purdue's OxyContin, an extended release formulation of oxycodone, and by Purdue's aggressive marketing of OxyContin. Other Manufacturer Defendants followed suit and began to aggressively market their own prescription opioids in a similar manner. The rapid acceleration of sales and use of prescription opioids continued for two decades, as alleged more fully below.

187. During this time, the Manufacturer Defendants individually and collectively poured vast financial resources into marketing opioid products in order to distort the pre-existing medical and public perceptions of prescription opioids as dangerous and addictive, creating the false impression of a new "consensus" supporting the long-term daily use of opioids. The Manufacturer Defendants' false and deceptive tactics were wide-reaching and varied.

188. The Manufacturer Defendants made these false and deceptive statements concerning both their own branded opioids and prescription opioids generally. The Manufacturer Defendants made these misrepresentations directly in their oral and written marketing to prescribers, as well as indirectly through the use of third-party vehicles, including: (i) so-called "key opinion leaders" ("KOLs"), *i.e.*, physicians who influence their peers' medical practices and prescribing behavior, who wrote favorable journal articles and delivered supportive educational courses; (ii) "unbranded" educational materials for patients, physicians and others disseminated through groups purporting to be independent patient-advocacy and professional organizations ("Front Groups"), which exercised influence through Defendant-controlled KOLs who served in leadership roles in these organizations and which were directly or indirectly controlled by the

Manufacturer Defendants; (iii) a body of biased and unsupported scientific literature which the Manufacturer Defendants directly or indirectly created, funded, or exploited; (iv) so-called "treatment guidelines" which the Manufacturer Defendants formulated or caused to be formulated and distributed or caused to be distributed; and (v) CMEs prepared and/or funded in whole or in part by the Manufacturer Defendants. These third parties and third-party vehicles are collectively referred to herein as the Manufacturer Defendants' "Third-Party Allies."

189. The Manufacturer Defendants' direct and indirect marketing through their Third-Party Allies was very effective. The Manufacturer Defendants' efforts successfully altered the prescribing practices of the medical community, thereby dramatically increasing opioid prescriptions and use. These efforts also successfully influenced third-party payors, pharmacy benefit managers ("PBMs") and others responsible for maintaining and administering drug formularies on behalf of private and public health insurance plans.

190. A 2016 joint investigation conducted by the Associated Press and the Center for Public Integrity found that opioid manufacturers and allied groups spent more than $880 million over the past decade to influence state governmental policies in order to promote opioids. [29] Those manufacturers, including the Manufacturer Defendants, used the same deceptive practices and communications to influence policymakers, as well as the public.

191. In Pennsylvania, Defendant Purdue sat on a 38-member opioid task force and advisory committee chaired by a state legislator. After the group met in private with no publicly available transcripts or minutes of its meetings, it recommended that legislators enact a bill to promote abuse-deterrent opioids. The House held no public hearing on the bill, and the bill passed

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[29] Marc Levy, Pennsylvania Opioid Debate May Include Push for Pricier Pill, The Morning Call (Sept. 18, 2016), http://www.mcall.com/news/nationworld/pennsylvania/mc-pa-politics-of-pain-pennsylvania-20160917-story.html.

the Pennsylvania House 190-3. However, Defendants' representations that abuse-deterrent formulations could help thwart addiction were deceptive and without scientific support. [30] The end result was simply that Defendants could charge more for their supposed "abuse-deterrent" pills, thus allowing them to reap even greater profits as a result of the addiction crisis that they created.

192. Over-prescription of opioids resulting from the deceptive over-promotion by the Manufacturer Defendants led to an artificial inflation of demand for prescription opioids, including the creation of a population of users physically dependent on opioids, thereby leading to dramatically increased sales of prescription opioids, all to the improper and direct financial benefit of the Manufacturer Defendants.

193. The Manufacturer Defendants' broad false and deceptive marketing efforts have, indeed, been enormously profitable. In 2015 alone, prescription opioids generated $9.6 billion in revenue for opioid manufacturers.[31] From 1996 to 2000, OxyContin sales increased from $48 million to almost $1.1 billion and did not decrease.[32] Defendant Purdue generated $35 billion alone in revenue from the sale of OxyContin from the product's inception to 2016.[33]

194. The vast demand for opioids today is sustained largely by the Manufacturer Defendants' prior success in false and deceptive marketing in establishing prescription opioids as a treatment for chronic pain. The current demand for prescription opioids is driven, to a significant extent, by individuals suffering from physiological dependence who require continued opioid prescriptions (and their agent-doctors who refill opioid prescriptions in the continued belief that

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30 *Id.*

31 D. Crow, Drugmakers Hooked on $10bn Opioid Habit, Financial Times (Aug. 10, 2016), https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

32 Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99(2): 221-227, Am. J. Public Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

33 Patrick Radden Keefe, The Family That Built an Empire of Pain, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

opioids are safe in light of the Manufacturer Defendants' prior product promotion, as well as the Distributor and Pharmacy Defendants' misleading statements and conduct described in more detail below) and new patients who, along with their physicians, wrongly believe that opioids are a viable and safe chronic pain treatment, among others.

195. The Manufacturer Defendants directed their false and deceptive marketing efforts not only to physicians, pharmacists and patients, but also to third-party payors, PBMs and other health plan administrators, including those responsible for approving the Manufacturer Defendants' drugs for inclusion on drug formularies.

196. Physicians, along with formulary committees of third-party payors and PBMs, rely upon a variety of sources including independent studies for information relating to the safety and efficacy of prescription drugs, which they prescribe or approve for use. However, often unbeknownst to the public and other persons and entities, many of these sources are directly controlled or heavily influenced by pharmaceutical manufacturers such as the Manufacturer Defendants. Also, many of these sources of information are susceptible to exploitation by pharmaceutical manufacturers such as the Manufacturer Defendants.

197. The Manufacturer Defendants' violations of the law are not excused by the involvement of doctors in the prescription process or clinical evaluators at the third-party payors, PBMs or other health plan administrators, because they themselves were subject to and influenced by the Manufacturer Defendants' false and deceptive marketing. The Manufacturer Defendants' widespread and highly persuasive messages tainted many sources on which doctors and health plan administrators relied for information, and prevented them from making fully informed treatment decisions. The Manufacturer Defendants improperly targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the Manufacturer Defendants' misleading

statements, as well as clinical evaluators at or used by health plan administrators.

A. The Manufacturer Defendants Used "Branded" and "Unbranded" Opioid Marketing to Deceive Physicians, Patients and PBMs

198. Drug companies' promotional activities can be characterized as "branded" or "unbranded." Branded marketing refers to marketing of a specific drug manufactured by a specific company. Unbranded marketing does not refer to the marketing of a specific drug or brand, but rather to a class of drugs, or to a particular disease, condition, or treatment.

199. The Manufacturer Defendants made false and deceptive statements in their branded marketing as alleged below. In addition to direct statements concerning safety and efficacy and in connection with their branded marketing, the Manufacturer Defendants also brought to the attention of their target audience – physicians, patients, third-party payors, PBMs and others – the unbranded marketing alleged below.

1. The Manufacturer Defendants' Deceptive Branded Marketing of Opioids

200. The Manufacturer Defendants' branded marketing, by law, generally must not include false or misleading statements or material omissions about the safety and/or efficacy of the drug.

201. Drug companies, which are regarded as most knowledgeable about the properties and effects of their drugs, are responsible for providing prescribers, third-party payors, PBMs and other health plan administrators with information they need to accurately assess the risks and benefits of drugs for their patients and insureds.

202. The Manufacturer Defendants' product marketing and promotional statements that fail to state accurately the safety, efficacy and risks of a prescription drug or that fail to present the most important risks of the drug as prominently as its benefits are deceptive on their face or because they lack fair balance.

203. It is also deceptive for the Manufacturer Defendants to distribute materials or make promotional statements that exclude contrary evidence or information about the drug's safety or efficacy, or present conclusions that cannot be supported by the results of clinical or other studies.

204. Further, it is deceptive for the Manufacturer Defendants to make comparisons between their drugs and other drugs that represent or suggest that their drugs are safer or more effective than other drugs that treat the same condition, when they have not been demonstrated to be safer or more effective based on substantial evidence or substantial clinical experience.

205. To spread their false and deceptive messages supporting chronic opioid therapy, the Manufacturer Defendants marketed their branded opioids directly to health care providers nationwide and in the Clearfield County area. They did so principally through their sales force – sales representatives, also known as "detailers" -- who made in-person sales calls to prescribers in which they misleadingly portrayed their branded opioids as safe, effective, and appropriate for the treatment of chronic pain.

206. For years, the Manufacturer Defendants relied heavily on their sales representatives to market opioids directly to prescribers and others, and that practice continues today, including in the Clearfield County area. For example, in 2014, the Manufacturer Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. As another example, in 2016, Purdue spent $156 million on detailing out of $167 million in total advertising expenditures promoting opioids nationwide. Expenditures of these magnitudes are more than double the Manufacturer Defendants' collective spending on detailing in 2000. By establishing personal relationships with doctors and other prescribers, the Manufacturer Defendants' sales representatives are able to disseminate their misrepresentations in targeted, one-on-one settings.

207. The Manufacturer Defendants employed the same marketing tactics and messages in the Clearfield County area as they did regionally and nationwide, using uniform marketing materials and national and regional sales training. The Manufacturer Defendants carefully trained their sales representatives to deliver company-approved sales messages. The Manufacturer Defendants exactingly directed and monitored their sales representatives – through detailed action plans, trainings, tests, scripts, role-plays, and supervisor tag-alongs – to ensure that individual sales representatives actually delivered the Manufacturer Defendants' desired messages.

208. The Manufacturer Defendants encouraged or required their sales representatives to make in-person detailing visits to multiple prescribers per day. Many of these prescribers were visited repeatedly, often monthly or more frequently. In addition, detailers often had to meet individual sales quotas.

209. The Manufacturer Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. The Manufacturer Defendants purchased and closely analyzed prescription sales data from IMS Health (the largest vendor of physician prescribing data to the medical community). This data allowed them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allowed them to target, tailor, and monitor the impact of their detailing efforts.

210. The Manufacturer Defendants relied upon "influence mapping," i.e., using rankings or similar breakdowns to identify high-volume prescribers on whom detailing would have the greatest sales impact. Endo, for example, identified prescribers representing 30% of its nationwide opioid sales volume and planned to visit those physicians three times per month. The Manufacturer Defendants also closely monitored doctors' prescribing activity after a sales representative's visit to allow the Manufacturer Defendants to refine their planning and messaging and to evaluate and compensate their detailers.

211. During the relevant time period, Manufacturer Defendants' sales representatives made thousands of detailing visits to physicians in Pennsylvania, including in Clearfield County. They spread misinformation regarding the risks, benefits, and superiority of Defendants' opioids for treatment of chronic pain.

212. The Manufacturer Defendants collectively spent hundreds of millions of dollars promoting opioid drugs via their respective sales forces, including in Clearfield County, because they knew their sales strategies were highly effective. Numerous studies indicate that marketing by drug manufacturers influences doctors' prescribing habits. Face-to-face detailing typically has the highest influence of any marketing practice on a physician's intent to prescribe. The Manufacturer Defendants saw this phenomenon at work not only in the aggregate, as their sales climbed with promotional spending, but also at the level of individual prescribers they targeted for detailing who responded by prescribing more opioid drugs to more patients.

213. In addition to making deceptive claims in-person through detailers, the Manufacturer Defendants engaged in printed advertising campaigns touting the benefits of their branded opioids, including in Clearfield County. The Manufacturer Defendants published print advertisements in a broad array of medical journals ranging from those aimed at specialists, such as the *Journal of Pain and Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Several of the Manufacturer Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo. Actavis' and Cephalon's medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

214. The Manufacturer Defendants were deliberately deceptive in their portrayal of the risks and benefits of chronic opioid therapy in these branded advertisements. For example, in 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients. And a 2005 ad that ran in pain medicine journals misleadingly implied that OxyContin could lead to long-term improvement in patients' pain, function, and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a man and a boy fishing under the tagline "There Can Be Life With Relief." The ads falsely implied that OxyContin provides effective long-term pain relief as well as functional improvement, claims that are unsubstantiated and contradicted in medical literature. Upon information and belief, these ads were circulated in the Clearfield County area.

215. The Manufacturer Defendants also engaged in branded marketing to physicians through voice mail, postcards, and email – so-called "e-detailing."

2. The Manufacturer Defendants' Deceptive Unbranded Marketing of Opioids

216. In addition to direct branded product promotion, the Manufacturer Defendants disseminated false, misleading, and unsubstantiated statements on a massive scale through unbranded marketing materials – that is, materials that promoted prescription opioid use but did not identify a specific opioid drug. Through these unbranded materials and statements, the Manufacturer Defendants presented information and guidelines concerning prescription opioids generally that were false and misleading.

217. Furthermore, by acting through third parties, the Manufacturer Defendants were able to give the false appearance that their messages reflected the views of independent, unbiased sources.

218. The Manufacturer Defendants falsely cited to these sources as "independent" corroboration of their own statements.

219. The Manufacturer Defendants' engineered third-party documents and marketing not only had greater credibility, but also broader diffusion among practitioners in the medical profession. Generally, doctors did not resist receiving materials from purportedly independent entities on display in their offices, as they might with drug company pieces.

220. The Manufacturer Defendants disseminated many of their false, misleading, and unsubstantiated promotional messages through their Third-Party Allies because the messages appeared to uninformed or misled observers to be independent. Through unbranded materials, the Manufacturer Defendants presented information and guidance concerning opioids that were false, misleading, unsubstantiated, and/or incomplete, including in the Clearfield County area.

221. Even where the Manufacturer Defendants disseminated unbranded messages through their Third-Party Allies, the Manufacturer Defendants adopted those messages as their own when they cited to, edited, approved, and distributed such materials in their direct marketing activities knowing they were false, misleading, unsubstantiated, and/or incomplete.

222. As described herein, the Manufacturer Defendants' sales representatives regularly distributed false and deceptive third-party marketing materials to the Manufacturer Defendants' target audiences, including physicians, patients, and others such as pharmacy benefit managers, formularies, insurers, third-party payors, health plan administrators and other participants in the prescribing third-party approval chain, including in the Clearfield County area.

223. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that the Manufacturer Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, the Manufacturer Defendants exercised control over their

deceptive messages and acted in concert with these third parties to promote the use of prescription opioids for the treatment of chronic pain.

224. The unbranded marketing materials that the Manufacturer Defendants assisted in creating and disseminating failed to disclose properly the risks of opioid addiction, abuse, misuse, and overdose, or wrongfully denied or minimized those risks as alleged more fully herein. Those materials also misrepresented or concealed information concerning the efficacy of prescription opioids as a treatment for chronic pain.

B. The Manufacturer Defendants' Use of Key Opinion Leaders to Further Their Deceptive Marketing

225. The Manufacturer Defendants cultivated a select group of doctors who were chosen and sponsored by the Manufacturer Defendants solely because they favored the aggressive treatment of chronic pain with prescription opioids. Pro-opioid doctors were the hub of the Manufacturer Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. Doctors hired by pharmaceutical companies to influence prescribing practices of their peers are known as key opinion leaders or KOLs.

226. These pro-opioid doctors wrote, consulted on, edited, and lent their names to numerous books and articles, and gave speeches and Continuing Medical Education courses ("CMEs") supportive of opioid therapy for treatment of chronic pain.

227. The KOLs served on committees that developed so-called "treatment guidelines" that strongly encouraged the use of prescription opioids to treat chronic pain, and on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs, including in Pennsylvania. The Manufacturer Defendants were able to exert control of each of these modalities through their KOLs.

228. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. It is now clear that written and oral statements by the Manufacturer Defendants' KOLs were false and/or misleading or lacked reasonable medical or scientific basis in fact.

229. The Manufacturer Defendants cited and promoted their KOLs – and studies or articles by their KOLs – to broaden the chronic opioid therapy market. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate the publications or studies of doctors who were critical of the use of chronic opioid therapy.

230. The Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Manufacturer Defendants' agenda. The Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs.

231. In their promotion of the use of opioids to treat chronic pain, the Manufacturer Defendants' KOLs knew or recklessly disregarded the possibility that their statements were false and misleading, but they continued to deliver their misleading messages to benefit themselves and the Manufacturer Defendants. Two of the Manufacturer Defendants' most prominent KOLs are described below.

1. Dr. Russell Portenoy's Role in the Manufacturer Defendants' Deceptive Marketing of Opioids

232. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaigns.

233. Dr. Portenoy received research support, consulting fees, and honoraria from Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to

Cephalon and Purdue.

234. Dr. Portenoy was instrumental in opening the door for the regular use of prescription opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of prescription opioids to treat chronic pain first in 1997 and again in 2009. He was also a member of the board of American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

235. Dr. Portenoy also made frequent media appearances promoting prescription opioids and spreading misrepresentations on the Manufacturer Defendants' behalf.

236. For example, he appeared on *Good Morning America* in 2010 to discuss the use of opioids to treat chronic pain. On this widely watched program, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[34]

237. Dr. Portenoy subsequently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[35] Among other things, these lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors that promoted them overstated opioids' benefits and glossed over their risks.

238. Dr. Portenoy also conceded to *The Wall Street Journal* that "[d]ata about the

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34 *Good Morning America* television broadcast, ABC News (Aug. 30, 2010).

35 Thomas Catan *et al.*, A Pain-Drug Champion Has Second Thoughts, The Wall Street Journal (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

effectiveness of opioids does not exist."[36] He candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[37]

239. Bloomberg reported that Dr. Portenoy "recanted publicly in 2011, conceding that research he relied on to push his and Purdue's pro-opioid campaign didn't prove anything about the treatment of chronic pain."[38]

2. Dr. Lynn Webster's Role in the Manufacturer Defendants' Deceptive Marketing of Opioids

240. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, a small pain clinic in Salt Lake City, Utah. In 2013, Dr. Webster was the President and a former board member of AAPM, a front group that ardently supports chronic opioid therapy. He was a Senior Editor of *Pain Medicine*, the same journal that published Defendant Endo's special advertising supplements touting Opana ER.

241. Dr. Webster taught numerous CMEs sponsored by Defendants Cephalon, Endo, and Purdue. At the same time, Dr. Webster received significant funding from the Manufacturer Defendants, including nearly $2 million from Defendant Cephalon.

242. Dr. Webster was investigated by the DEA for overprescribing opioids. The DEA raided his clinic in 2010.[39] More than 20 of Dr. Webster's former patients at the Lifetree Clinic died of opioid overdoses.

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[36] *Id.*

[37] *Id.*

[38] Esme Deprez, The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry, Bloomberg Businessweek (Oct. 5, 2017), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

[39] Stephanie Smith, Prominent Pain Doctor Investigated by DEA After Patient Deaths, CNN (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

243. Dr. Webster created and promoted the Opioid Risk Tool,[40] a ten question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appeared on, or were linked to, websites run by Defendants Endo, Janssen, and Purdue.

244. In 2011, Dr. Webster presented, via webinar, a program sponsored by Defendant Purdue titled *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was – and still is –available to doctors nationwide.[41]

245. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of *undertreated* pain. In Dr. Webster's description, the only way to differentiate between addiction and undertreated pain was to increase a patient's dose of opioids. As he and his co-author wrote in a book titled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[42]

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[40] Lynn R. Webster, The Opioid Risk Tool, https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

[41] Managing Patient's Opioid Use: Balancing the Need and the Risk, Emerging Solutions to Pain (Nov. 1, 2011), http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209.

[42] *See* Lynn R. Webster, Avoiding Opioid Abuse While Managing Pain (2007), excerpt available at https://books.google.com/books?id=1C_DRcKq_KwC&pg=PT99&lpg=PT99&dq=%22Avoiding+Opioid+Abuse+While+Managing+Pain%22+%22clinician%E2%80%99s+first+response%22&source=bl&ots=DctEK1gFua&sig=IQiikIPhKQldfmLayEF-YlDTRfo&hl=en&sa=X&ved=0ahUKEwiZ7aep78DWAhVl0FQKHUF3CjUQ6AEIJjAA

Defendant Endo distributed this book to many doctors.

246. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[43]

247. Doctors Portenoy and Webster are only two examples of KOLs and their cooperation with the Manufacturer Defendants. On information and belief, a number of other similarly compromised KOLs also cooperated with the Manufacturer Defendants.

248. Misleading statements and materials created by KOLs were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

249. Between August of 2013 and December of 2015, more than 375,000 opioid-related payments were made to more than 68,000 physicians in the U.S. One in twelve physicians, and one in five family doctors, accepted a payment related to a prescription of opioid from 2013 to 2015.[44]

#v=onepage&q=%22Avoiding%20Opioid%20Abuse%20While%20Managing%20Pain%22%20%22clinician%E2%80%99s%20first%20response%22&f=false.

[43] John Fauber *et al.*, Networking Fuels Painkiller Boom, Milwaukee Wisconsin Journal Sentinel (Feb. 19, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

[44] David Orenstein, Opioids Makers Made Payments to One in Twelve U.S. Doctors, New from Brown University (Aug. 9, 2017), https://news.brown.edu/articles/2017/08/opioids-influence.

C. *The Manufacturer Defendants' Misuse of Patient and Physician Education Materials and Front Groups to Further Their Deceptive Marketing of Opioids*

250. Pharmaceutical industry marketing experts view patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[45]

251. Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true for opioids and conditions for which they are not approved.[46]

252. Recognizing this phenomenon, the Manufacturer Defendants worked with Front Groups to engage in largely unbranded marketing directly to patients about opioid treatment for chronic pain.

253. The Manufacturer Defendants entered into arrangements with numerous Front Groups to promote opioids. These organizations depended upon the Manufacturer Defendants for significant funding and, in some cases, for their survival.

254. The Front Groups generated materials and programs for doctors and patients that supported chronic opioid therapy, responded to unfavorable articles about the dangers of prescription opioids, and lobbied against regulatory changes that would constrain opioid prescribing.

255. The Front Groups developed and disseminated pro-opioid treatment guidelines; conducted outreach to patient groups targeted by the Manufacturer Defendants, such as veterans

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[45] Kanika Johar, An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices, 76 Albany L. Rev. 299, 308 (2013).

[46] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, Effects of Patient Medication Requests on Physician Prescribing Behavior, 52(2) Med. Care 294 (2014).

and the elderly; and developed and sponsored CMEs that focused exclusively on use of prescription opioids to treat chronic pain.

256. The Manufacturer Defendants funded the Front Groups to ensure the delivery of favorable messages from seemingly neutral and credible third parties.

257. The following are examples of the Front Groups used by the Manufacturer Defendants to further their deceptive marketing:

1. The American Pain Foundation's Role in Defendants' Deceptive Marketing of Opioids

258. APF, the most prominent of the Front Groups, received more than $10 million in funding from opioid manufacturers from 2007 until it ceased operations in May 2012.

259. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of prescription opioids for chronic pain and trivialized the risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign through radio, television and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

260. All of APF's programs and materials were intended to, and did, reach a national audience, including within Clearfield County.

261. By 2011, APF was dependent on grants from Defendants Purdue, Cephalon and Endo for funding, which also enabled APF to avoid using its line of credit. APF board member, KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

262. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying efforts against various legislative initiatives that would limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of the Manufacturer

Defendants, not patients.

263. In practice, APF operated in close collaboration with the Manufacturer Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by the Manufacturer Defendants. APF also assisted in marketing projects for the Manufacturer Defendants.

264. The close relationship between APF and the Manufacturer Defendants demonstrates APF's clear lack of independence in its finances, management, and mission. APF's willingness to allow the Manufacturer Defendants to control its activities and messages indicates that each Defendant that worked with it was able to exercise editorial control over its publications.

265. In May 2012, the U.S. Senate Finance Committee began investigating APF to determine the links, financial and otherwise, between the organization and manufacturers of opioid painkillers.

266. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[47]

2. The American Academy of Pain Medicine's Role in the Manufacturer Defendants' Deceptive Marketing of Opioids

267. The AAPM, with the assistance, prompting, involvement and funding of the Manufacturer Defendants, issued the treatment guidelines discussed above, and sponsored and hosted CMEs essential to Defendants' marketing plans.

268. AAPM received over $2.2 million in funding since 2009 from the Manufacturer Defendants and other drug manufacturers.

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[47] Charles Ornstein and Tracy Weber, American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics, ProPublica (May 8, 2012), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

269. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California – or other resort locations.

270. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented marketing programs to doctors who attended this annual event.

271. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – for example 37 out of roughly 40 sessions at one conference alone addressed opioids.

272. AAPM's list of past presidents includes top industry-supported KOLs Dr. Portenoy, Dr. Perry Fine, and Dr. Lynn Webster. Dr. Webster was elected president of AAPM while the DEA was investigating his practice.

273. AAPM's staff understood that they and their industry funders were engaged in a common task. The Manufacturer Defendants were able to influence AAPM through substantial funding and the leadership of pro-opioid KOLs within the organization.

D. The Manufacturer Defendants' Corruption of Scientific Literature to Further Their Deceptive Marketing of Opioids

274. Rather than actually study the safety and efficacy of opioids for long-term use, the Manufacturer Defendants deceived physicians, patients, and health plan administrators into believing that such studies had already been conducted.

275. The Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the

effectiveness of long-term opioid use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions and purchasing decisions of prescribers, patients, and health care payors. This literature was, in fact, marketing material intended to persuade doctors, patients, and third-party payors that the benefits of long-term prescription opioid use outweighed the risks.

276. To accomplish their goal, the Manufacturer Defendants – sometimes through their Third-Party Allies or other third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of misleadingly favorable articles in academic journals.

277. The articles did not originate in professional organizations that engaged in research, development, or any other area that would confer specialized knowledge about opioid drugs. Rather, these purportedly academic articles originated in the Manufacturer Defendants' marketing departments and with the Manufacturer Defendants' marketing and public relations consultants.

278. One commentator noted, regarding the pharmaceutical industry generally: "To give you an idea of how much the drug industry values sales and advertising, the fact is that Big Pharma spends more on that than on actual drug research and development."[48]

279. In these marketing materials, the Manufacturer Defendants or their surrogates often claimed to rely on "data on file" or presentation posters, neither of which was subject to peer review or other scientific safeguards or reliability. Still, the Manufacturer Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that the Manufacturer Defendants' materials were not based on reliable data or the use of normal practices of scientific safeguards to assure reliability and were not subject to the scrutiny of others who are experts in the same field.

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[48] Jake Novak, Big Pharma's Opioid Mess is About to Hit the Industry – Hard, CNBC (Oct. 18, 2017), https://www.cnbc.com/2017/10/18/how-opioid-crisis-will-crush-big-pharma-commentary.html.

280. The Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study.

281. Notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine – J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter") – in a manner that makes it appear that the item reported the results of a peer reviewed study. The Manufacturer Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter to the editor, not a study, much less a peer-reviewed study. The letter merely states that the authors examined their files of hospitalized patients who were prescribed opioids and summarized what they found. The Porter & Jick Letter is reproduced here, in its entirety:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: **Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.**

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154 **Boston University Medical Center**

1. **Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.**
2. **Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.**

282. The patients referred to in the Porter & Jick Letter were all treated prior to 1980 when the letter was published. Because of standards of care prior to 1980, the use of opioid

treatment was limited to acute or end-of-life situations, as opposed to long-term use for chronic pain.

283. The letter notes that the authors found almost no references in patient records to signs of addiction. However, there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor is there any indication whether the patients were monitored after they were discharged from the hospital.

284. None of these serious limitations was disclosed when the Manufacturer Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are safe and rarely addictive. Dr. Jick later complained that his letter had been distorted and misused.

285. The Manufacturer Defendants' campaign of misinformation continues. For example, a Purdue-funded study in 2017 in the *Journal of Managed Care & Specialty Pharmacy* stated: "[N]early 100 million Americans live with chronic pain . . . . For moderate to severe pain, opioids can provide significant symptom relief."[49] The study made no reference to the risks of using opioids or the distinction in both efficacy and risk between short-term and long-term use.

286. The Manufacturer Defendants wrongfully created and promoted favorable studies in medical literature and discredited or suppressed negative information about prescription opioids. The Manufacturer Defendants' studies and articles often had the goal of debunking articles that contradicted the Manufacturer Defendants' claims or raised concerns about chronic opioid therapy.

287. The Manufacturer Defendants' strategy – to plant and promote pro-opioid literature and then cite that evidence in their promotional materials, while failing to disclose evidence that

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[49] Noam Kirson *et al.*, The Economic Burden of Opioid Abuse: Updated Findings, Journal of Managed Care & Specialty Pharmacy, 427 (April 2017), http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

contradicted those claims – resulted in egregiously deceptive and misleading marketing and promotion. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding risks and benefits of prescription opioids for long-term pain relief.

288. The Manufacturer Defendants' false and deceptive statements and scientific literature were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

289. The Manufacturer Defendants' promotion of opioids via false, deceptive, misleading and incomplete statements in the medical and scientific literature did not stop at the physician level, but also was aimed at, and directly and indirectly received by, other participants in the opioid marketing process including third-party payers and PBMs. For example, as part of the formulary listing process described below, manufacturer representatives submitted written materials, such as formulary dossiers and other written descriptions of the drugs, which in turn incorporated misleading data concerning the particular drug.

290. The Manufacturer Defendants' representatives also disseminated other false, deceptive and misleading medical literature about opioids to third-party payors, PBMs and others, including so-called "studies" and other statements as alleged more fully herein that, in turn, relied on highly misleading statements concerning the alleged benefits and safety of opioids such as the Portenoy and Porter & Jick materials noted above.

E. The Manufacturer Defendants' Misuse of Treatment Guidelines and Consensus Statements to Further Their Deceptive Marketing of Opioids

291. "Treatment guidelines" and consensus statements have been particularly important in securing acceptance for long-term opioid therapy. They are relied upon by doctors, especially

general practitioners and family doctors targeted by the Manufacturer Defendants, who generally are not experts and have no special training in the treatment of chronic pain.

292. Treatment guidelines and consensus statements not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and are relied on by third-party payors and PBMs in determining whether prescription opioids can be listed as approved pain relievers and whether they should pay for treatments for specific indications.

1. The Federation of State Medical Boards Was a Target of the Manufacturer Defendants' Deceptive Marketing of Opioids

293. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States, including medical boards in Pennsylvania and the Clearfield County area. State boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

294. Defendants Purdue, Endo, and Cephalon have provided grants to the FSMB to finance opioid-specific and pain-specific programs.[50]

295. Since 1998, the FSMB has been developing state medical board policies for the use of opioids to treat pain. The 1998 version, titled *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("1998 Guidelines"), was produced "in collaboration with pharmaceutical companies." With the influence of the Manufacturer Defendants' marketing, the 1998 Guidelines provided not that opioids could be appropriate in limited cases after other pain treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

296. A 2004 version of the 1998 Guidelines, and a 2007 book titled *Responsible Opioid*

[50] Ltr. from FSMB to U.S. Senate regarding Senate review of opioid abuse issues, 11-14, (June 8, 2012), https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

Prescribing: A Physician's Guide ("Responsible Opioid Prescribing"), also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach and did reach physicians nationwide, including in Pennsylvania.

297. The publication and distribution of *Responsible Opioid Prescribing* was backed largely by drug manufacturers including some or all the Manufacturer Defendants. In all, 163,131 copies were distributed by state medical boards (and through the boards, to practicing doctors). Some 601 copies were distributed in Pennsylvania.[51]

298. Having influenced the 1998 Guidelines, the Manufacturer Defendants also used them to help convey the alarming message that "under-treatment of pain" could result in official discipline, and that no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

299. The Manufacturer Defendants' (and their Third-Party Allies') worked with the FSMB to turn doctors' fear of discipline on its head: doctors, who formerly believed that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be reprimanded if they failed to prescribe opioids to their patients with chronic pain.

2. American Academy of Pain Medicine/American Pain Society Guidelines' Role in Defendants' Deceptive Marketing of Opioids

300. The AAPM and APS are professional medical societies, each of which received substantial funding from the Manufacturer Defendants.

301. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[52] The chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid

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51 *Id.* at pg. 19.

52 The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997), http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf.

speaker for Purdue. The sole consultant to the committee was KOL Dr. Portenoy. The consensus statement, which also formed the foundation of the Defendant-influenced 1998 Guidelines, was published on the AAPM's website and distributed to new AAPM members until 2012.

302. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Defendants Janssen, Cephalon, Endo and Purdue.

303. The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel for Defendants and have influenced not only treating physicians, but also the body of scientific evidence addressing opioids. They were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were and are available online, and were made available nationwide and in Clearfield County.

304. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines as part of their false and deceptive marketing, without disclosing the lack of evidence to support their conclusions.

305. Treatment guidelines and consensus statements were disseminated directly or indirectly to third-party payors and PBMs as part of the Manufacturer Defendants' deceptive marketing to formularies.

F. The Manufacturer Defendants' Misuse of Continuing Medical Education Programs to Further Their Deceptive Marketing

306. A CME is a professional education program provided to doctors. CMEs are analogous to continuing legal education programs provided to attorneys. Doctors are required to attend a certain number – and often type – of CME programs each year as a condition of licensure.

307. These programs are delivered in person (often in connection with professional organizations' conferences), online, or via written publications.

308. Doctors rely on CMEs not only to satisfy licensing requirements, but also to obtain information on new developments in medicine or to deepen their knowledge in specific areas of practice.

309. CMEs were often taught by KOLs who are highly respected in their fields, and were thought to reflect these physicians' medical expertise, thus CMEs were especially influential with doctors.

310. The countless doctors and other health care professionals who attend or view accredited CMEs constituted an enormously important audience for opioid education.

311. As one target, the Manufacturer Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs. As a result, general practitioners were especially susceptible to the Manufacturer Defendants' deceptive marketing.

312. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the biased messages described throughout this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

313. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[53]

314. On information and belief, physicians and others involved in health plan administration, such as pharmacy benefit managers, formulary personnel and others in Clearfield County and nationwide, attended or reviewed the Manufacturer Defendants' sponsored CMEs as the use and abuse of prescription opioids skyrocketed as alleged more fully *infra*.

315. By sponsoring CME programs provided by Front Groups like APF, AAPM and others, the Manufacturer Defendants expected instructors to deliver messages favorable to the Manufacturer Defendants, as these organizations were dependent on the Manufacturer Defendants for funding and other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct, immediate, and inherent effect on prescribers' views of opioids.

316. Producers of CMEs and the Manufacturer Defendants measured the effects of CMEs on prescribers' views on opioids, and prescribers' receptivity to and absorption of specific messages, confirming the strategic marketing purpose in supporting them and helping the Manufacturer Defendants sharpen their CME marketing campaign going forward.

G. Purdue's New Advertising Campaign that Seeks to Salvage Its Public Image While Continuing to Mislead the Public

317. Beginning in or around December 2017, Purdue placed full-page advertisements in

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[53] Opinion 9.0115, Financial Relationships with Industry in CME, Am. Med. Ass'n, 1 (Nov. 2011), http://www.msma.org/uploads/6/2/5/3/62530417/ama_ethical_opinion_9.0115_financial_relationships_with_industry_in_cme.doc.

the *New York Times* and other major newspapers that misrepresented the nature and import of purported safety measures taken by Purdue. The ads falsely claimed that the company and its products were "research-driven" and "science based." The ads utterly failed to mention Purdue's deceptive tactics for obtaining research and publications that supported its profit-driven motives, or that Purdue pleaded guilty in 2007 to "mislabeling" painkillers and paid more than $600 million in damages.

318. On July 19, 2018, Purdue placed a full-page ad in the *Washington Post* stating: "We are acutely aware of the public health risks opioid analgesics can create, even when taken as prescribed." Only five days later, Purdue published the same ad in the same paper, omitting the phrase "when taken as prescribed."[54]

III. THE MANUFACTURER DEFENDANTS' WIDELY DISSEMINATED MISREPRESENTATIONS AND OMISSIONS CREATED A LIKELIHOOD OF CONFUSION OR MISUNDERSTANDING AS TO THE SAFETY AND EFFICACY OF OPIOIDS FOR LONG-TERM USE

319. The Manufacturer Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and through third parties, included information that was false, deceptive, misleading, contrary to credible scientific evidence, and lacked balance and substantiation.

320. The Manufacturer Defendants' misrepresentations and omissions were part of an organized effort to penetrate the market for pain medication and convince prescribers, third-party payors, PBMs, and the public that opioids can and should be used to treat chronic pain. To this end, the Manufacturer Defendants' false and deceptive marketing materials omitted material

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[54] Fred Schulte, Purdue Pharma Edits Public Service Ad in Washington Post, The Washington Post (July 24, 2018), https://www.washingtonpost.com/national/health-science/purdue-pharma-edits-public-service-ad-in-washington-post/2018/07/24/2f1ddefc-8f7c-11e8-ae59-01880eac5f1d_story.html?utm_term=.05442c556889. *Compare* https://kaiserhealthnews.files.wordpress.com/2018/07/july19_purdue.pdf *to* https://kaiserhealthnews.files.wordpress.com/2018/07/july24_purdue.pdf.

information about the risks of opioids, and overstated their benefits. They also inaccurately suggested that long-term opioid therapy was supported by evidence, and consistently failed to disclose the lack of evidence in support of treating long-term pain with opioids.

321. These misrepresentations and omissions were specifically directed at a broad target audience that included consumers and providers such as physicians and pharmacists, as well as pharmacy benefit managers and other insurers and reimbursement professionals.

322. There are seven primary categories of false, deceptive, misleading and unfounded representations that the Manufacturer Defendants engaged in individually, collectively, and in conjunction with purportedly independent third parties. Specifically, the Manufacturer Defendants:

a. misrepresented that opioids improve effectively treat patients' pain and improve their function and quality of life;

b. downplayed the link between long-term use of opioids and addiction;

c. misrepresented that addiction risk can be effectively managed;

d. masked the signs of addiction by promoting the misleading concept of "pseudoaddiction";

e. falsely claimed that opioid withdrawal symptoms can be easily addressed;

f. misrepresented that increasing doses of opioids poses no significant additional risks of abuse, addiction, or death; and

g. overstated the risks and understated the efficacy of non-opioid based alternative pain treatments.

323. Exacerbating each of these misrepresentations or omissions was the collective effort of the Manufacturer Defendants and their Third-Party Allies to hide from the medical community material facts, including, for example, that there actually was – and is – an absence of

"adequate and well-controlled studies of opioid use longer than 12 weeks."[55]

324. All of these misrepresentations and omissions, as alleged in further detail below, were false and deceptive to both ordinary consumers and the other members of the Manufacturer Defendants' target audience, including prescribers, insurers, third-party payors, PBMs and other health plan administrators. The overall impression arising from the totality of what the Manufacturer Defendants said – as well as what their statements and omissions reasonably implied – created a likelihood of misunderstanding, uncertainty, and confusion regarding the safe, recommended, and medically sound therapeutic uses of opioids to treat chronic pain.

325. The Manufacturer Defendants' misrepresentations and omissions were not only likely to, but did in fact, deceive and mislead consumers, insurers, PBMs and other health plan administrators and others into believing that opioids, when used to treat chronic pain, would be beneficial to patients' health, functioning, and quality of life, and would not lead to abuse or addiction, even at increasing doses. The Manufacturer Defendants' target audience was further deceived and misled into believing that alternative, non-opioid pain treatments were inferior, ineffective, and unsafe.

326. The Manufacturer Defendants disseminated their misrepresentations directly, and indirectly through Third-Party Allies, including KOLs and Front Groups. In disseminating these misrepresentations to the Manufacturer Defendants' benefit, these Third-Party Allies, while purporting to be independent patient-advocacy and professional organizations, in fact acted at the Manufacturer Defendants' behest and direction as the Manufacturer Defendants' agents or servants

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[55] Ltr. from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013), (hereinafter "Woodcock Ltr., Sept. 10, 2013"), http://docplayer.net/36264645-The-petition-requests-pertain-to-analgesia-products-therefore-this-response-is-limited-to-opioids-with-indications-for-analgesia.html.

within the course and scope of their agency or service. The Manufacturer Defendants accordingly are responsible for the conduct of their Third-Party Allies as alleged herein.

327. The Manufacturer Defendants failed to correct their misrepresentations and omissions and failed to instruct their Third-Party Allies to correct them. On information and belief, the Manufacturer Defendants' deceptive and misleading conduct is ongoing.

A. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Misrepresented that Prescription Opioids Improve Patients' Ability to Function and Improve their Quality of Life

328. The Manufacturer Defendants' created each of the documents and other materials (or other similar documents) outlined below to promote opioid use so that doctors would prescribe them, patients would actively seek them, and insurers and health plan administrators would approve the drugs for inclusion in – and payment or reimbursement from – private and public health plans. These materials also encouraged doctors and others to continue or approve long-term use of opioid therapy in the belief that failure to improve pain, function, or quality of life with initial doses of opioids could be overcome by increasing doses or prescribing additional short-acting opioids on an as-needed basis for breakthrough pain.

329. In addition, and as further alleged previously, the Manufacturer Defendants ignored not only that there was no evidence that opioids improved long-term functioning, but also a 2006 study of other studies that found that "[f]or functional outcomes . . . other [non-opioid] analgesics were significantly more effective than were opioids."[56]

330. As further alleged previously, studies of the use of opioids for chronic conditions

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[56] Andrea D. Furlan *et al.*, Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects, 174(11) Can. Med. Ass'n J. 1589-1594 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. For example, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not lead patients to return to work or physical activity.[57] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly worse on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[58]

331. As further alleged previously, long-term use of opioids exposes users to a host of known, serious risks, including risks of misuse, abuse, addiction, overdose, and death. Chronic opioid therapy can also cause side effects, including mental clouding and confusion, sleepiness, hyperalgesia, constipation, and immune-system and hormonal problems, that degrade, rather than improve, patients' ability to function. The Manufacturer Defendants purposefully and intentionally omitted these adverse effects, as well as certain risks of drug interactions, from their publications and marketing efforts.

332. Each of the following specific statements by the Manufacturer Defendants in their deceptive marketing of opioids falsely suggests that the long-term use of opioids actually improve patients' function and quality of life, and that scientific evidence supports such claims.

333. These statements, which were directly contrary to the facts, created confusion and

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[57] BA Martell *et al.*, Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction, Annals of Internal Medicine (2007), http://annals.org/aim/article-abstract/732048/system-review-opioid-treatment-for-chronic-back-pain-prevalence-efficacy-association?volume=146&issue=2&page=116.; Richard Deyo *et al.*, Opioids for Low Back Pain, BMJ Publishing (Jan. 5, 2015), http://www.bmj.com/content/350/bmj.g6380.

[58] Survey: Migraine Patients Taking Potentially Addictive Barbiturate or Opioid Medications Not Approved by FDA as Migraine Treatments, (May 15, 2017), https://www.thefreelibrary.com/Survey%3A+Migraine+Patients+Taking+Potentially+Addictive+Barbiturate+or+...-a0163389345.

misunderstanding as to the purported benefits of chronic opioid therapy, and in particular the ability of opioids to improve both patients' ability to function and their quality of life. The deceptive and misleading statements influenced consumers' and others' purchasing, prescribing, and reimbursing decisions, since they were designed to convince these members of the Manufacturer Defendants' target audiences that opioids were safe and effective, and to lead them to choose opioids over alternative treatments and therapies for chronic pain:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy."[59] b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of long-term Kadian therapy, including physical, social, vocational, and recreational function.[60] c. Actavis distributed a product brochure and detailing document that claimed that use of Kadian to treat chronic pain would relieve "stress on your body and your mental health," allow patients to avoid "miss[ing] work," and cause patients to better enjoy their lives.[61] Government regulators warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . , results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[62] The regulators concluded that the representations were "false or misleading because they omit and minimize the serious risks associated with the drug, . . . and present unsubstantiated superiority and effectiveness claims. . . . These violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[63] d. On information and belief, Actavis sales representatives told prescribers that prescribing Actavis' opioids would improve their patients' ability to function and improve their quality of life.

[59] *City of Chicago v. Purdue Pharma et al.*, No. 14-cv-04361 (N.D. Ill.), Third Amended Complaint at ¶ 221, Oct. 25, 2016 (Dkt. 478) (hereinafter "*Chicago v. Purdue* Third Amend. Compl., Oct. 25, 2016), http://www.feinberg.northwestern.edu/sites/ipham/conferences/globalhealthsymposium/docs/Third_Amended_Complaint_14_cv_04361.pdf.

[60] *Id.*

[61] Warning Letter from Thomas Abrams, Dir., FDA Div. of Marketing, Advertising and Communications, to Doug Boothe, CEO, Actavis U.S. (Feb. 18. 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

[62] *Id.*

[63] *Id.*

Teva/Cephalon	e. Cephalon sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[64] Cephalon spent $150,000 to purchase copies of this book in bulk and distribute it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.[65] f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve."[66] The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report.[67] The publication is currently available online.[68] g. Cephalon sponsored a CME written by KOL Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 to December 15, 2008.[69] The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. h. Cephalon's 2006 marketing plan for marketing of Fentora, which was reviewed and approved at the highest levels of the company's management, was aimed at various types of pain management, including for "chronic pain patients," among other things. The marketing focus was to "generate awareness, understanding, and appropriate use of [Fentora] for breakthrough pain." A "target patient" was the patient "suffering from chronic pain."[70] i. On information and belief, Cephalon sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

[64] Peter R. Wilson, Responsible Opioid Prescribing. A Clinician's Guide, Section Edition Revised & Expanded, 16:5 J Pain Medicine 1027, 1028 (May 2015) https://academic.oup.com/painmedicine/article/16/5/1027/2460527/Responsible-Opioid-Prescribing-A-Clinician-s-Guide; *Chicago v. Purdue* Third Amend Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.

[65] *Id.*

[66] Treatment Options: A Guide for People Living with Pain, American Pain Foundation, https://ce4less.com/Tests/Materials/E019Materials.pdf.

[67] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.

[68] Treatment Options, *supra* note 66.

[69] Lynn Webster, Optimizing Opioid Treatment for Breakthrough Pain, Medscape CME & Education (2007), https://www.medscape.org/viewarticle/563417_6.

[70] Cephalon 2006 Marketing Plan for Fentora, quoted in *U.S. v. Cephalon, Inc.*, No. 09-cv-02926 (E.D. Pa.) Fifth Amended Qui Tam Complaint at ¶ 66 (Sept. 13, 2013).

Endo	j. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."[71] Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. k. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."[72] l. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work, for example as a chef.[73] The flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[74] m. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[75] n. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in original).[76] *Exit Wounds* omitted warnings of the risk of interactions between opioids and benzodiazepines, which increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. o. On information and belief, Endo sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Janssen	p. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally."[77] The myth/fact structure implies authoritative backing for the claims, which does not exist. The targeting of older adults also ignored heightened opioid risks in this population. q. Janssen sponsored, developed, and approved content of the website *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* was financed and orchestrated by Janssen. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying that her experience would be representative of what other patients can expect to experience.[78] This video is still available today on youtube.com.[79] r. Janssen provided grants to APF to distribute to veterans the book *Exit Wounds*, which taught that opioid medications "*increase* your level of functioning" (emphasis in original).[80] *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. s. On information and belief, Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

[71] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.
[72] *Id.* at ¶ 221.
[73] *Id.* at ¶ 221.
[74] Warnings or limitations generally must be given equal prominence in product disclosures.
[75] Wilson, *supra* note 64; *Chicago v. Purdue* Third Amend. Compl at ¶ 221, Oct. 25, 2016, *supra* note 59.
[76] Derek McGinnis, Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families (2009).
[77] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.
[78] *Id.* at ¶ 221.
[79] https://www.youtube.com/user/LetsTalkPain.
[80] McGinnis, *supra* note 76.

Purdue	t. Purdue's unbranded website *In the Face of Pain* (inthefaceofpain.com) contained testimonials from various "Advocates" who commented about opioids. One such advocate, Dr. Russell Portenoy, advocated the use of opioids because, in his words: "The negative impact of unrelieved pain on the lives of individuals . . . is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern."[81] This statement was available on inthefaceofpain.com through at least 2014 and 2015.[82] The New York Attorney General reached a settlement agreement with Purdue in 2015 regarding the misleading nature of these representations. See discussion *infra*. u. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain Vignettes." They were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, Paul, is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.[83] v. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in "improving daily function, psychological health, and health-related quality of life for chronic pain patients."[84] The guide is currently available online.[85] w. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve."[86] APF distributed 17,200 copies in one year alone, according to its 2007 annual report.[87] The guide is currently available online.[88] x. Purdue sponsored APF's book *Exit Wounds* (2009), which taught veterans that opioid medications "*increase* your level of functioning" (emphasis in original).[89] *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. y. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[90] Purdue also spent over $100,000 to support distribution of the book.[91] z. On information and belief, Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

[81] Settlement Agreement between New York Attorney General and Purdue Pharma, at pg. 7 (Aug. 19, 2015), hereinafter "NYAG-Purdue Settlement Agreement, Aug. 19, 2015"), https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf.

[82] *Id.* at pg. 7.

[83] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.

[84] A Policymaker's Guide to Understanding Pain & Its Management, American Pain Foundation, https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[85] *Id.*

[86] Treatment Options, *supra* note 66.

[87] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016 *supra* note 59.

334. These statements reached the Manufacturer Defendants' target audiences nationwide and in Clearfield County as intended.

B. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Failed to Disclose the Truth about the Risk of Addiction from Long-Term Opioid Use

335. The Manufacturer Defendants' failure to disclose the risks that opioids are highly addictive was central to Defendants' deceptive marketing.

336. To reach chronic pain patients, the Manufacturer Defendants and their Third-Party Allies had to overcome doctors' legitimate fears that patients would become addicted. The risk of addiction is an extremely weighty risk, condemning patients to a disease that is chronic, progressive – and, if not properly treated, often fatal. In addition, addiction recovery carries a lifetime risk of battling relapse.

337. Absent the Manufacturer Defendants' deceptive campaigns to convince doctors otherwise, it would be highly unlikely for a reasonable physician to find that the benefits from long-term opioid use for many aspects of chronic pain sufficiently outweighed the risks of addiction to justify writing the prescription.

338. Through their well-funded, widespread, and comprehensive marketing efforts, the Manufacturer Defendants and their KOLs, Front Groups and other Third-Party Allies were able to change prescriber perceptions, despite the well-settled historical understanding and clear evidence that there is substantial risk of addiction associated with long-term opioid use.

339. The Manufacturer Defendants and their Third-Party Allies: (a) maintained that the

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[88] Treatment Options, *supra* note 66.
[89] McGinnis, *supra* note 76.
[90] Wilson, *supra* note 64; *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.
[91] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 59.

risk of addiction for patients who take opioids long-term was low; and (b) failed to properly disclose the addiction risk as an adverse effect, even though the frequency and magnitude of the risk compelled disclosure.

340. The Manufacturer Defendants also used code words that conveyed to prescribers and patients that their product was less prone to abuse and addiction than competitors' products. For example, sales representatives for Defendants Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties, claiming that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction.

341. Defendant Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting that Endo had succeeded in making the drug harder to adulterate and abuse.[92] In fact, however, the clinical significance of Endo's crush-resistant formulation or its impact on abuse and misuse has not been established for Opana ER, and Opana ER could still be ground and cut into small pieces by those looking to abuse the drug.

342. Defendant Purdue falsely suggested that OxyContin was less likely to be abused.

343. Each of the statements alleged herein was created by the Manufacturer Defendants with the expectation that, by instructing prescribers and patients that addiction rates are low, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue – APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011) – claimed that opioids were not prescribed often enough because of "misconceptions about opioid addiction."[93]

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[92] Endo Pharmaceuticals, Approval of a New Formulation of Opana ER Designed to be Crush Resistant, PR Newswire Association (Dec. 12, 2011), https://www.prnewswire.com/news-releases/endo-announces-fda-approval-of-a-new-formulation-of-opana-er-designed-to-be-crush-resistant-135431073.html.

[93] Policymaker's Guide, *supra* note 84.

344. Acting directly or with and through third parties, each Manufacturer Defendant falsely claimed that the potential for addiction from opioids was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. For example, a 2015 literature survey found that rates of "misuse" averaged between 21% and 29%, and rates of "addiction" ranged between 8% and 12%.[94] These estimates are well in line with Purdue's own undisclosed studies, showing that between 8% and 13% of OxyContin patients became addicted,[95] but on which Purdue chose not to rely, instead citing the Porter & Jick letter as evidence of non-addiction.

345. According to the FDA, 26% of opioid patients obtain opioids from two or more prescribers, 16.5% seek early refills, and 20% use two or more pharmacies – all potential "red flags" for abuse or addiction.[96] Regulators in fact have ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that they found "high rates of addiction" in the medical literature.[97]

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[94] Kevin Vowles *et al.*, Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: a Systematic Review and Data Synthesis, 156 PAIN 569-76 (April 2015), https://30qkon2g8eif8wrj03zeh041-wpengine.netdna-ssl.com/wp-content/uploads/2017/12/PCSS-O-Vowles-Opioid-Use-04-11-2017.pdf. .

[95] Lawrence Robbins, Long-Acting Opioids for Severe Chronic Daily Headache, 10(2) Headache Quarterly 135 (1999); Lawrence Robbins, Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache, 19 Headache Quarterly 305 (1999).

[96] Len Paulozzi, M.D., Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse, https://wayback.archive-it.org/7993/20170405203727/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM233244.pdf.

[97] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf; Woodcock Ltr., Sept. 10, 2013, *supra* note 55.

346. The significant and growing incidences of abuse, misuse, and addiction to opioids are also powerful evidence that the Manufacturer Defendants' statements regarding the low risk of addiction were, and are, untrue. The Manufacturer Defendants had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

347. Acting directly or through and with third parties, the Manufacturer Defendants claimed in their deceptive marketing that the potential for addiction from long-term use of opioids was relatively small or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. The Manufacturer Defendants' efforts to trivialize and conceal the potential for abuse and addiction posed by opioids were intended to deceive and mislead consumers by falsely suggesting that patients need not worry about addiction risks when using opioids for chronic pain management.

348. The Manufacturer Defendants' misrepresentations in this regard included:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction.[98] b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is "less likely if you have never had an addiction problem."[99] The overall presentation suggests the risk is so low as not to be a concern. c. Kadian sales representatives told prescribers that Kadian was "steady state" and had extended-release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused.[100] d. Kadian sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused, and thereby less addictive, than other opioids.[101] e. Actavis sales representatives omitted any discussion with prescribers of addiction

98 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
99 *Id.*
100 *Id.*
101 *Id.*

	risks related to Kadian. In fact, a July 2010 "Dear Doctor" letter mandated by government regulators required Actavis to acknowledge to the doctors to whom it marketed its opioid drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."[102] f. On information and belief, Allergan/Actavis sales representatives omitted any discussion of addiction risks when discussing Allergan/Actavis opioid products with prescribers.
Cephalon	g. Cephalon sponsored and facilitated the development of a guidebook titled *Opioid Medications and REMS: A Patient's Guide*, which claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."[103] h. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.[104] The guide is currently available online.[105] i. On information and belief, Cephalon sales representatives omitted any discussion of addiction risks when discussing Cephalon's opioid products with prescribers.
Endo	j. On Endo's website www.opana.com, Endo claimed until at least April 2012 that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[106] The New York Attorney General investigated this statement, found that Endo had no evidence for the statement, and reached a settlement with Endo requiring corrective action.[107] See discussion *infra*. k. Similarly, Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[108] The New York Attorney General found that those statements were unwarranted. See discussion *infra*. l. Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, conveying that it was less likely to be abused. This claim was false. Government regulators warned in a May 10, 2013 letter that there was no evidence that Endo's design would "provide a reduction in oral, intranasal or

[102] *State of Ohio v. Purdue Pharma. et al.*, Common Pleas Court, Ross County, Ohio (May 31, 2017), Complaint ¶ 40, *available at* http://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2017-05-31-Final-Complaint-with-Sig-Page.aspx.

[103] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.

[104] Treatment Options, *supra* note 66.

[105] *Id.*

[106] Settlement Agreement between New York Attorney General and Endo, at ¶ 20 (March 1, 2016) (hereinafter "NYAG-Endo Settlement Agreement, March 1, 2016"), https://ag.ny.gov/pdfs/New_York_Settlement_Agreement.pdf.

[107] *Id.* at ¶ 20.

[108] *Id.* at ¶ 22.

	intravenous abuse," and that Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." [109] m. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[110] The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. n. Endo sponsored a website, PainAction.com, which stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[111] o. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult and Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients," which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.[112] p. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction, stating: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."[113] q. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems."[114] This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. It is still available online today.[115] r. Endo contracted with the American Geriatrics Society ("AGS") to produce a CME promoting the 2009 Guidelines, titled *Pharmacological Management of Persistent Pain in Older Persons* (2009). The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[116] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek

[109] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[110] *Id.*
[111] *Id.*; Joanne Zeis, Opioid Medication and Addiction, Pain Action (Oct. 2015), https://www.painaction.com/opioid-medication-addiction/.
[112] *Id.*
[113] *Id.*
[114] Endo Pharmaceuticals, Understanding Your Pain: Taking Oral Opioid Analgesics, (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.
[115] *Id.*
[116] Pharmacological Management of Persistent Pain in Older Persons, 57: 8 JAGS 1331-1346 (2009), https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.

	drug company funding to promote them after their completion. s. Endo sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[117] t. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[118] The overall presentation suggests that the risk is so low as not to be a concern. u. On information and belief, Endo sales representatives omitted discussion of addiction risks related to Endo's opioid drugs when discussing Endo's opioid products with prescribers.
Janssen	v. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[119] The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem. w. Janssen contracted with AGS to produce a CME promoting the 2009 Guidelines, titled *Pharmacological Management of Persistent Pain in Older Persons*. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[120] The study supporting this assertion does not analyze addiction rates by age. As previously noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug-company funding to promote them after their completion. x. Janssen provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[121] The overall presentation suggests that the risk is so low as not to be a worry. y. Janssen ran a website, Prescriberesponsibly.com, which claimed that concerns about opioid addiction are "overstated."[122] z. A June 2009 Nucynta training module warned Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed."[123]

[117] *Chicago v. Purdue* Third Amend. Compl, at ¶ 229, Oct. 25, 2016, *supra* note 59.
[118] McGinnis, *supra* note 76.
[119] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[120] Pharmacological Management of Persistent Pain in Older Persons, *supra* note 111.
[121] McGinnis, *supra* note 76.
[122] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[123] *Id.*

	aa. Janssen sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[124] bb. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to these drugs. In truth, however, as set out in Nucynta's product label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit."[125] cc. Janssen's sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug.[126] dd. On information and belief, Janssen sales representatives omitted discussion of addiction risks related to Janssen's opioid drugs when discussing Janssen's opioid products with prescribers.
Purdue	ee. A 2017 study funded by Purdue to analyze medical costs associated with opioid addiction noted: "[N]early 100 million Americans live with chronic pain . . . . For moderate to severe pain, opioids can provide significant symptom relief."[127] The study made no reference to the distinction in addiction risks between short-term and long-term use. ff. Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse* (2011), which under the heading "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa.[128] In fact, opioid users who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.[129] Thus, these representations deceptively reassured doctors that, as long as they do not observe those signs of misuse, they need not be concerned that patients are abusing or addicted to opioids. gg. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that less than 1% of children prescribed opioids will become addicted.[130] The publication also asserted that pain is "undertreated" due to "misconceptions about opioid addiction." The guide is currently available online.[131] hh. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of

[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] Noam Kirson *et al.*, The Economic Burden of Opioid Abuse: Updated Findings, Journal of Managed Care & Specialty Pharmacy, 427 (April 2017), http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.
[128] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[129] Purdue itself acknowledged in October 2010 that OxyContin was used non-medically by injection 4-17% of the time. *See Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[130] Policymaker's Guide, *supra* note 84.
[131] *Id.*

	unauthorized dose escalations, obtaining opioids from multiple sources, or theft. The guide is currently available online.[132] ii. A Purdue-funded study with a Purdue co-author claimed that "evidence of the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[133] The study relied only on the Porter & Jick letter to the editor concerning a review of charts of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. The overall presentation suggests that the risk is so low as not to be a worry. jj. Purdue contracted with AGS to produce a CME promoting the 2009 Guidelines titled *Pharmacological Management of Persistent Pain in Older Persons*. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[134] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. Purdue trained sales representatives to target physicians treating elderly patients for conditions like osteoarthritis. In internal documents, Purdue admitted that opioids are not appropriate for the treatment of a specific disease such as osteoarthritis. kk. Purdue sponsored APF's book *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[135] The overall presentation suggests that the risk is so low as not to be a concern. ll. Purdue sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[136] mm. Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a "buzz" from increased dosage.[137] nn. Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by drug addicts, and, therefore, less likely to be abused or diverted, or result in addiction.[138] oo. Purdue sales representatives emphasized that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide slow-onset, stable doses without "peaks and valleys" – encouraging prescribers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction. In a 2011 sales training document,

[132] Treatment Options, *supra* note 66.
[133] Peter Watson *et al.*, Controlled-Release Oxycodone Relieves Neuropathic Pain: A Randomized Controlled Trial in Painful Diabetic Neuropathy, 105 Pain 71 (2003), https://pdfs.semanticscholar.org/be4f/ff311b5869e11245dbc5ed433e59035d0f9c.pdf.
[134] Pharmacological Management of Persistent Pain in Older Persons, *supra* note 111.
[135] McGinnis, *supra* note 76.
[136] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[137] *Id.*
[138] *Id.*

	Purdue acknowledged that the "fewer peaks and valley" message seen in a review of sales representative call notes was "problematic" – confirming both that the statements were made and that they were false.[139] pp. On information and belief, Purdue sales representatives omitted discussion of addiction risks related to Purdue's opioid drugs when discussing Janssen's opioid products with prescribers.

349. These statements reached the Manufacturer Defendants' target audience nationwide and in Clearfield County as intended.

350. Rather than honestly disclose the risk of opioid abuse and addiction in their marketing materials, the Manufacturer Defendants and their Third-Party Allies improperly portrayed those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe long-term opioid therapy, Defendants deceptively suggested that doctors who did not treat their patients' chronic pain with opioids were failing their patients, and would potentially be subject to discipline

351. The Manufacturer Defendants and their Third-Party Allies also claimed that overblown worries about addiction caused pain to be *under-treated* and caused opioids to be *under-prescribed* and over-regulated. This claim reinforced Defendants' marketing messages that the risks of addiction and abuse were exaggerated and not significant.

352. For example, Janssen's website *Let's Talk Pain* warned in a video posted online that: "[S]trict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in

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[139] *Attorney General of New Jersey v. Purdue Pharma, LP*, No. 245-17 (N.J. Super. Ct. Ch. Div. 2017), Complaint at ¶ 83; Dustin Racioppi, New Jersey Sues Drug Company Purdue Pharma in Crisis, North Jersey.Com (Oct. 31, 2017), http://www.northjersey.com/story/news/new-jersey/2017/10/31/nj-sues-another-drug-company-opioid-crisis/816924001/.

silence."[140] The program continued on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing environment is one of many barriers that may contribute to the under-treatment of pain, a serious problem in the United States."[141]

353. Similarly, a Purdue website called *In the Face of Pain*, under the heading "Protecting Access," complains that, through mid-2013, policy governing the prescribing of opioids was "at odds" with best medical practices by: (i) "unduly restricting the amounts that can be prescribed and dispensed;" (ii) "restricting access to patients with pain who also have a history of substance abuse;" and (iii) "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[142] This unsupported and untrue rhetoric aimed to portray doctors who did not prescribe opioids as ignoring industry best practices, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

C. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Misrepresented that Opioid Addiction Risk Can Be Avoided or Managed

354. The Manufacturer Defendants continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain why doctors encounter so many patients addicted to opioids, the Manufacturer Defendants and their Third-Party Allies admit that some patients may become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. The Manufacturer Defendants claim that these tools can identify patients at high risk for addiction (stemming, for example, from personal or family histories of substance abuse or mental illness) so that doctors can more closely

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[140] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[141] *Id.*
[142] *Id.*

monitor those patients.

355. The Manufacturer Defendants' marketing claims that doctors can readily identify and manage addiction risk are not true. There is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction, and there is no scientific evidence that screening or any other precautions can remove the risk of addiction.

356. Despite the use of screening tools, patients with past substance use disorders – which every tool rates as a risk factor – receive, on average, higher doses of opioids from their physicians.

357. In addition to making deceptive representations about screening, Defendant Purdue deceptively marketed "abuse-deterrent" opioids – a reformulated version of OxyContin and Hysingla ER – in a manner that falsely implied these drugs can curb abuse and even addiction. Beginning in 2010, Purdue claimed that abuse and addiction result from "product diversion," meaning that abusers tended to snort or inject opioids rather than ingest the drugs orally. Purdue falsely assured prescribers and other members of its target audiences that its new formulation, which made its opioid pills more difficult to crush or inject, would prevent or reduce misuse, abuse, or diversion.

358. Specifically, Purdue and its sales representatives falsely claimed or implied that Purdue's abuse-deterrent formulations: (i) prevented tampering and cannot be crushed or snorted; (ii) prevented or reduced opioid abuse, diversion, and addiction overall; and (iii) were safer than other opioids. At the same time, Purdue either failed to disclose that the abuse-deterrent formulations did not impact the most common forms of abuse – oral ingestion – or affirmatively misrepresented that most abuse is by non-oral means.[143]

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[143] *Attorney General of New Jersey v. Purdue Pharma, LP*, No. 245-17 (N.J. Super. Ct. Ch. Div. 2017), Complaint at ¶ 124; Racioppi, *supra* note 139.

359. In fact, there is no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the 2016 CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[144]

360. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly harmful because it persuaded doctors, who might otherwise curtail their opioid prescribing, to continue prescribing Purdue's opioids in the mistaken belief that they were safer. It also allowed prescribers, patients, and other members of Purdue's target audience to discount evidence of opioid addiction and attribute it to other, less safe opioids – *i.e.,* to believe that while patients might abuse or overdose on non-abuse deterrent opioids, Purdue's opioids did not carry that risk.

361. A 2014 *Evidence Report* by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain," identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[145]

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[144] *CDC Guideline,* March 18, 2016, 22, *supra* note 14; *see also* Theodore J. Cicero & Matthew J. Ellis, Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin, 72(5) JAMA Psychiatry 424-430 (May 2015).

[145] The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain, Agency for Healthcare Research and Quality (Sept. 19, 2014), https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatment_research.pdf.

362. The Manufacturer Defendants' representations that the risk of addiction could be readily avoided or managed, and Purdue's representations that its abuse-deterrent formulations could help thwart addiction and abuse, were deceptive and without scientific support, as described below. These misrepresentations by the Manufacturer Defendants were intended to persuade prescribers, patients, and health care payors to choose opioid drugs over competing medications and therapies. Their marketing claims misled consumers into believing that addiction, misuse, and abuse could easily be avoided or managed. The Manufacturer Defendants' misrepresentations were not only likely to, but did in fact, influenced the purchasing and prescribing decisions of patients, doctors, and other third-party payors, by downplaying the risks associated with using opioids instead of other pain relief therapies to treat chronic pain.

363. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.[146]
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."[147] The guide is currently available online.
Endo	c. Endo paid for a 2007 supplement available for CME credit in the Journal of Family Practice. This publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.[148]
Purdue	d. Purdue's unbranded website *In the Face of Pain* (inthefaceofpain.com) stated that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds" with best medical practices.[149] The New York Attorney General reached a settlement agreement with Purdue in 2015 regarding the misleading nature of this website. The New York Attorney General found that the website created a false impression of impartiality and concealed that Purdue made significant financial contributions to

146 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
147 Treatment Options, *supra* note 66.
148 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
149 *Id.*

	many paid speakers whose testimonials appeared on the website.[150] See discussion *infra*. e. Purdue sponsored a CME program taught by a KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes* (2012). This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.[151] f. Purdue sponsored a 2011 webinar taught by KOL Dr. Webster, titled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."[152] g. On information and belief, Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. h. On information and belief, Purdue sales representatives told prescribers that Purdue's abuse-deterrent formulations of its oral opioids OxyContin and Hysingla are more difficult to abuse and less likely to be diverted.

359. These statements reached the Manufacturer Defendants' target audience nationwide and in Clearfield County as intended.

D. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Created Confusion as to Opioid Addiction Risks by Promoting the Misleading Concept of "Pseudoaddiction"

364. The Manufacturer Defendants and their Third-Party Allies developed and disseminated each of the following misrepresentations about "pseudoaddiction" so that, by instructing patients and prescribers that signs of addiction are actually the product of under-treated pain, doctors would prescribe more opioids to more patients and continue prescribing them, and patients would continue to use opioids despite signs of addiction.

365. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to

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[150] NYAG-Purdue Settlement Agreement (Aug. 19, 2015), 7-8, *supra* note 81.

[151] Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes, (Oct. 11, 2012), https://docmh.com/chronic-pain-management-and-opioid-use-easing-fears-managing-risks-and-improving-outcomes-pdf.

[152] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.

work for Purdue, and popularized by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, blurring the line between undertreated pain and true addiction, as if patients could not experience both.

366. KOL Dr. Webster subsequently conceded that: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept."[153] Despite this partial confession, the Manufacturer Defendant continued and even increased their marketing campaign to downplay the risks of addiction.

367. Each of the Manufacturer Defendants' statements identified below falsely or deceptively states or suggests that the concept of pseudoaddiction is substantiated by scientific evidence and accurately describes the condition of undertreated patients who need, and should be treated with, higher dosages of opioids. These misrepresentations, intended to and did persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies. In addition, the Manufacturer Defendants' deceptive marketing regarding "pseudoaddiction" influenced the purchasing and prescribing decisions of patients, doctors, and other third-party payors, and downplayed the true risks of addiction and convinced the public to choose opioids over other pain relief therapies.

368. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	i. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."[154]
Cephalon	j. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative

[153] John Fauber *et al.*, Networking Fuels Painkiller Boom, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012), http://bangordailynews.com/2012/02/19/health/networking-fuels-painkiller-boom/.
[154] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.

	behavior," seeing more than one doctor to obtain opioids, and hoarding opioids are all signs of "pseudoaddiction."[155] Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.[156]
Endo	k. Endo distributed copies of a book by KOL Dr. Webster titled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents described the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and that "increasing the dose in most cases . . . should be the clinician's first response."[157] l. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."[158] m. Endo trained its sales representatives to distinguish addiction from "pseudoaddiction." The New York Attorney General reached a settlement with Endo in 2016 regarding this representation and others, finding that "the 'pseudoaddiction' concept has never been empirically validated and in fact has been abandoned by some of its proponents."[159] See discussion *infra*.
Janssen	n. From 2009 to 2011, Janssen's website *Let's Talk Pain* stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."[160]
Purdue	o. Purdue sponsored three articles in *The Atlantic*, including an article published in 2017 written by Gerald Aronoff, M.D. entitled *Take My Pain Away . . . A Physician's Perspective of Prescription Opioids and Pain Management*, which created the impression that opioid medications were safe and effective for the treatment of chronic pain, and that newer abuse-deterrent opioid formulations were safer. This article was false and misleading. It appeared again in *The Atlantic* in 2017. p. Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse* (2011), which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [addictive drug-seeking behaviors] in patients who have pain that has not been effectively treated."[161] q. Purdue distributed to physicians, and posted on its unbranded website *Partners Against Pain,* a pamphlet titled *Clinical Issues in Opioid Prescribing* (2006). This pamphlet included a list of conduct, including "illicit drug use and deception," that it defined as indicative of "pseudoaddiction" or undertreated pain. It also stated: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. . . . Even such behaviors as illicit drug use and

155 *Id.*
156 *Id.*
157 *Id.*
158 *Id.*
159 NYAG-Endo Settlement Agreement, (March 1, 2016), at ¶ 23, *supra* note 106.
160 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
161 *Id.*

	deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."[162]
	r. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids, are all signs of "pseudoaddiction."[163] Purdue also spent over $100,000 to support distribution of the book.
	s. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which stated: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."[164] The guide is currently available online.

369. These statements reached the Manufacturer Defendants' target audience nationwide and in Clearfield County as intended.

E. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Falsely Claimed that Opioid Withdrawal Symptoms Can Be Readily Managed

370. In an effort to further downplay the risks and devastating impact of addiction, the Manufacturer Defendants and their Third-Party Allies frequently claimed that physiological dependence on opioids can be adequately addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal.

371. The Manufacturer Defendants and their Third-Party Allies promoted this false and misleading message so that prescribers and patients would be more likely to initiate long-term opioid therapy and would fail to recognize the actual risk of addiction.

372. The Manufacturer Defendants failed to properly disclose that discontinuing long-term use of opioids can be very difficult. These effects make it less likely that patients will be able to stop using opioids.

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[162] *Id.*

[163] Wilson, *supra* note 64; *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.

[164] Policymaker's Guide, *supra* note 84.

373. In truth, physiological dependence on opioids starts to develop after a few days of regular use. In a report by the University of Arkansas for Medical Sciences, even a one-day opioid prescription carried a 6% risk of use at least one year later and a 2.9% risk of use at least three years later. Researchers also found that the sharpest increases in the likelihood of long-term use came at five days after the initial prescription, with another spike seen at one month.[165] Individuals given a month-long prescription were 30% likely to be using prescription opioids a year later. Common withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain, among other things.[166]

374. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to return to opioids.

375. Each of the Manufacturer Defendants' representations below falsely states or suggests that opioid withdrawal was manageable, so that physicians and users would increase opioid use.

376. The Manufacturer Defendants' misrepresentations, intended to persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead the Manufacturer Defendants' target audience about the difficulty of treating and managing withdrawal in opioid users.

377. The Manufacturer Defendants' misrepresentations were not only likely to, but did in fact, influence the purchasing and prescribing decisions of patients, doctors, and other third-

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165 Jessica Wapner, CDC Study Finds Opioid Dependency Begins Within A Few Days of Initial Use, Newsweek (Mar. 22, 2017), https://www.newsweek.com/cdc-opiate-addiction-572498.

166 *See, e.g.*, Health Guide: Opiate Withdrawal, The New York Times (2013), http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

party payors.

378. The Manufacturer Defendants' deceptive marketing claims were intended to minimize the reality of managing withdrawal symptoms, and thereby encourage the public to choose opioids over other pain relief therapies and to continue taking, prescribing, or paying for opioids when used to treat long-term pain.

379. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to convey that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis' sales representative training also claimed that opioid withdrawal would take only a week, even in addicted patients.[167]
Endo	b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult,* taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.[168]
Janssen	c. A Janssen PowerPoint presentation used for training its sales representatives titled *Selling Nucynta ER* indicated that the "low incidence of withdraw symptoms" is a "core message" for its sales force. This message was repeated in numerous Janssen training materials between at least 2009 and 2011. The studies purportedly supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses, and would therefore not be representative of withdrawal symptoms in the patient population taking long-term opioids. Patients on long-term treatment will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied on a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use. Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window of severe withdrawal symptoms painted a misleading picture of the likelihood and severity of withdrawal associated with long-term opioid therapy. Janssen also knew or should have known that patients involved in the study were not taking the drug long enough to develop rates of withdrawal symptoms comparable to withdrawal symptoms suffered by patients who use opioids for chronic pain – a use for which Janssen promoted Nucynta ER.[169] d. Janssen sales representatives told prescribers that patients on Janssen's opioid drugs were less susceptible to withdrawal than those on other opioids.[170]
Purdue	e. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany

[167] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[168] *Id.*
[169] *Id.*
[170] *Id.*

	cessation of use.[171] The guide is currently available online. f. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans' low potency and its extended release mechanism.[172] g. In 2007, Purdue pled guilty to criminal charges stemming from its misleading marketing and promotion of OxyContin as having manageable withdrawal symptoms. Purdue admitted that it misrepresented to doctors that "patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug."[173] See discussion *infra*. h. On information and belief, Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be reasonably managed.

380. These statements reached the Manufacturer Defendants' target audience nationwide and in Clearfield County as intended.

F. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Falsely Minimized the Risks of Increasing Doses of Opioids Over Time

381. As part of their deceptive marketing campaign, the Manufacturer Defendants and their Third-Party Allies also claimed that prescribers and patients could increase doses of opioids indefinitely without added risk, even when increased doses failed to relieve pain or when doses reached levels that were "frighteningly high." The Manufacturer Defendants falsely suggested that patients would eventually reach a stable, effective dose as the dosage strength increased.

382. Each of the Manufacturer Defendants' misrepresentations omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

383. The Manufacturer Defendants made these misleading representations and omissions about the known risks of higher doses of opioids so that prescribers and patients would

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171 Policy Maker's Guide, *supra* note 84.
172 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
173 Purdue Guilty Plea, (May 10, 2007), https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt.

be more likely to continue to prescribe and use opioids. The misrepresentations also helped persuade physicians and patients not to discontinue opioids when patients' increased tolerance required them to seek higher doses.

384. In fact, patients that receive increasingly higher doses of opioids as part of long-term opioid therapy were three to nine times more likely to suffer an overdose than those on low doses. Compared to patients treated with non-opioid pain remedies, an opioid patient's tolerance to pain-reducing properties of opioids develops faster than tolerance to the adverse respiratory effects of opioids. Thus, continuously escalating opioid doses to respond to increased pain tolerance can lead to respiratory depression and death, even where opioids are taken as prescribed.

385. Moreover, patients are less likely to be able to terminate use of higher-dose opioids without severe withdrawal effects, leading patients to continue using opioids even when the drugs provide diminishing pain relief.[174]

386. Each of the false and deceptive representations by the Manufacturer Defendants and their Third-Party Allies downplayed the risks associated with increased doses of opioids. These misrepresentations were likely to, and did, confuse, deceive, and mislead the Manufacturer Defendants' target audience about the risks associated with higher doses of opioids to treat chronic pain. These misrepresentations and omissions were not only likely to, but did in fact, influence the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Manufacturer Defendants' misleading marketing promoted the message that patients would not be at risk if they continued to increase their doses of opioids. This misleading message influenced the Manufacturer Defendants' target audience to choose opioids over other, non-opioid treatments

[174] It is estimated that only 11.2% of the people who need treatment for opioid addiction will actually receive it. Of the people who do receive treatment, 90% will relapse within the first year of completing a traditional treatment program. *See* https://healthresearchfunding.org/24-opiate-addiction-recovery-statistics/.

and medications.

387. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	i. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis' opioid, Kadian.[175]
Cephalon	j. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.[176] The guide is currently available online. k. Cephalon sponsored a CME written by KOL Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC in 2007 and 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations, implying that opioids benefitted from less restrictive dose limitations.[177] l. On information and belief, Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.
Endo	m. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that opioids may be increased until "you are on the right dose of medication for your pain." Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.[178] n. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). It is still available online today.[179] In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."
Janssen	o. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines

[175] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[176] Treatment Options, *supra* note 66.
[177] Optimizing Opioid Treatment for Breakthrough Pain, *supra* note 69.
[178] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[179] Understanding Your Pain: Taking Oral Opioid Analgesics, *supra* note 114.

	and omitted any discussion of risks of increased doses of opioids.[180]
Purdue	p. Through at least June 2015, Purdue's website *In the Face of Pain*, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe what – in their view – is a sufficient dose of opioids, they should find another doctor who will increase the dosage.[181] In so doing, Purdue exerted influence over prescribers who face pressure to accede to the patients' demands for increased dosages. q. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones.[182] This falsely suggested that high dose opioids are safe and appropriate. It did not disclose the risks from high dose opioids. The guide is currently available online. r. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[183] The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language failed to disclose the heightened risks at elevated doses. The guide is currently available online. s. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled *Overview of Pain Management Options*, was edited by KOL Dr. Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses.[184] t. Purdue sales representatives told prescribers that high-dose opioids were effective for treating patients long-term, and omitted any discussion that increased tolerance would require increased – and increasingly dangerous – doses.[185]

388. These statements reached the Manufacturer Defendants' target audience nationwide and in Clearfield County as intended.

G. In Their Deceptive Marketing of Opioids, the Manufacturer Defendants and Their Third-Party Allies Overstated the Risks of Alternative Forms of Pain Treatment

389. The Manufacturer Defendants and their Third-Party Allies also misleadingly

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[180] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[181] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[182] Policymaker's Guide, *supra* note 84.
[183] Treatment Options, *supra* note 66.
[184] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[185] *Id.*

emphasized or exaggerated the risks of alternative therapies, such as non-opioid analgesics. These misrepresentations, which were intended to persuade prescribers, patients, and health care payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead the Manufacturer Defendants' target audience about the purported inferiority and dangers of non-opioid pain medications.

390. Further, these misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Manufacturer Defendants' misleading marketing was *specifically designed* to encourage the purchasing, prescribing, and reimbursing public to choose opioids over other pain relief therapies.

391. In overemphasizing the purported risks of non-opioid products, the Manufacturer Defendants and their Third-Party Allies routinely minimized or ignored the risks of long-term opioid therapy. These opioid risks –aside from the life-threatening risks associated with misuse, abuse, and addiction – include: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[186] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; Neonatal Abstinence Syndrome (when an infant exposed to opioids withdraws from the drugs after birth); and potentially fatal interactions with alcohol, benzodiazepines which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions), and other drugs, among other things.

392. Despite these serious risks, the Manufacturer Defendants asserted or implied that

[186] Woodcock Ltr., Sept. 10, 2013, *supra* note 55.

opioids were appropriate first-line treatments and safer than alternative non-opioid treatments, including non-steroidal anti-inflammatory drugs ("NSAIDs") such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose gastrointestinal, renal, and cardiac risks, particularly for elderly patients, the Manufacturer Defendants' exaggerated descriptions of those risks were improper, and made their omissions minimizing opioid risks all the more misleading.

393. As part of this marketing ploy, the Manufacturer Defendants and their Third-Party Allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000 to 20,000 deaths annually (more than opioids), when in truth the number is closer to 3,200.[187]

394. The Manufacturer Defendants' description of NSAID risks starkly contrasted with the Manufacturer Defendants' representation of opioid risks, which, according to the Manufacturer Defendants, included mostly mild conditions such as nausea, constipation, and sleepiness (but not addiction, overdose, or death). In fact, compared with NSAIDs, opioids are responsible for approximately four times as many fatalities annually.

395. As with the Manufacturer Defendants' other misrepresentations as alleged more fully herein, the Manufacturer Defendants' misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While the volume of opioid prescriptions has exploded over the past two decades, the use of NSAIDs has declined during that same time.[188]

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[187] Treatment Options, *supra* note 66, at 10; Courtney Krueger, Ask The Expert: Do NSAIDs Cause More Death than Opioids, Practical Pain Management (Nov. 2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

[188] Joseph Mercola, Many Back Pain Treatments Are Ineffective and Unnecessary, and Here's Why, Fitness Mercola (Aug. 16, 2013), https://fitness.mercola.com/sites/fitness/archive/2013/08/16/back-pain-overtreatment.aspx.

396. Each of the following representations by the Manufacturer Defendants and their Third-Party Allies reflects deceptive claims and omissions about the risks of opioids relative to NSAIDs:

Allergan/ Actavis	u. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs.[189] v. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons.[190] w. On information and belief, Actavis sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Cephalon	x. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[191] The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The guide is currently available online. y. On information and belief, Cephalon sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Endo	z. Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cited an example, meant to be representative, of a patient with a "massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years).[192] The study recommended treating the patient with opioids instead. aa. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer titled *Pain: Opioid Therapy*. This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.[193] bb. Endo provided grants to APF to distribute the book *Exit Wounds*

[189] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[190] *Id.*
[191] Treatment Options, *supra* note 66.
[192] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[193] *Id.*

	(2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[194] cc. On information and belief, Endo sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Janssen	dd. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase [in] the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness" (which the brochure claims will dissipate), and constipation.[195] ee. Janssen sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines.[196] *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[197] ff. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.[198] gg. On information and belief, Janssen sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Purdue	hh. Purdue sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[199] ii. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore

[194] McGinnis, *supra* note 76.
[195] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[196] McGinnis, *supra* note 76.
[197] McGinnis, *supra* note 76.
[198] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.
[199] McGinnis, *supra* note 76.

	the most appropriate treatment for severe pain.[200] The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The guide is currently available online. jj. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled *Overview of Management Options*, was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs, but not opioids, are unsafe at high doses.[201] kk. On information and belief, Purdue sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

397. These statements reached the Manufacturer Defendants' target audience nationwide and in Clearfield County as intended.

IV. CERTAIN DEFENDANTS ADMITTED THEIR DECEPTIVE MARKETING OF OPIOIDS IN PRIOR GUILTY PLEAS AND ATTORNEY GENERAL SETTLEMENTS BUT HAVE NEVERTHELESS CONTINUED SUCH PRACTICES

A. Purdue's 2007 Guilty Plea for OxyContin Marketing Misrepresentations

398. In 2007, Purdue and three top executives were indicted in Virginia and pled guilty to fraud in promoting OxyContin as non-addictive and appropriate for chronic pain.

399. As part of its guilty plea, Purdue admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:
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> * * *
>
> b. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
>
> c. [Purdue] sponsored training that taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than

[200] Treatment Options, *supra* note 66.

[201] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 59.

> immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> d. [Purdue] told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> e. [Purdue] told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[202]

400. Under the plea agreement, Purdue agreed to pay $600 million in criminal and civil penalties – one of the largest settlements up to 2007 for a drug company's marketing misconduct.[203] Also, Purdue's Chief Executive Officer, General Counsel, and Chief Medical Officer pled guilty and agreed to pay a total of $34.5 million in penalties.[204]

401. Prospectively, the guilty plea and consent decree required Purdue to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information.

402. Purdue's false and deceptive marketing continued even after the guilty plea and consent decree and continues to be a key factor in the current opioid epidemic in Clearfield County.

403. After the guilty plea, consent decree and penalties, rather than correct its misrepresentations and truly reform its conduct, Purdue instead built upon the deceptive messaging engaged in before which had established chronic opioid therapy as commonplace and reaped Purdue massive revenues. Since that time, and up to the present day, Purdue has both echoed the deceptions for which it was cited in 2007 and made diverse other misrepresentations in violation of the 2007 consent decree. Purdue has also continued to omit discussion of the serious risks of

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202 Purdue Guilty Plea, *supra* note 173.
203 *Id.*
204 *Id.*

opioids and lack of evidence supporting long-term opioid use – thereby failing to correct its prior deceptions, to its benefit – and to affirmatively misrepresent the risks and benefits of opioids for the treatment of chronic pain, all in violation of the 2007 consent decree.

404. Purdue's post-2007 conduct, including actions of its sales force, has impacted persons in Clearfield County.

405. Many Purdue sales representatives have operated in the Pennsylvania since 2007. Purdue's goal has been – and remains – that each of those representatives make in-person sales calls to multiple prescribers per day. Most of these prescribers were visited repeatedly – often monthly or even more frequently. Purdue assessed sales representatives' performance based on their ability to drive prescribing of the company's opioids; former Purdue detailers have reported having sales quotas of 500-700 OxyContin prescriptions per month.[205] On information and belief, similar sales quotas were imposed by Purdue on its sales representatives in Clearfield County.

406. Despite the 2007 guilty plea, and Purdue's firing of its sales force as of June 2018, on information and belief Purdue continues to disseminate false and misleading information about OxyContin and other opioids.

B. Purdue's 2015 Settlement with the New York Attorney General

407. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding Purdue's marketing of opioids.

408. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, the Purdue website www.inthefaceofpain.com failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's failure

[205] *See Attorney Gen. of State of N.J. v. Purdue*, No. 245-17 (Superior Ct. of N.J., Essex County), Complaint para. 76, *at* https://www.politico.com/states/f/?id=0000015f-72ce-db7b-afff-f7de399d0001.

to disclose these financial connections misled consumers regarding the objectivity of the testimonials.

409. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. . . . .
>
> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
>
> Although Purdue created the content on www.inthefaceofpain.com . . . the site creates the impression that it is neutral and unbiased. However, prior to this investigation, the website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost $231,000, for speaker programs, advisory meetings and travel costs, to 11 of the Advocates whose testimonials appeared on the site. The videos on YouTube also fail to disclose Purdue's payments to the Advocates.
>
> Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.[206]

410. As part of the settlement, Purdue agreed to make certain disclosures on www.inthefaceofpain.com and its similar websites, and to pay a monetary penalty.[207]

411. Purdue's improper marketing of opioids as alleged herein continued despite this settlement. As summarized in an October 30, 2017 article in *The New Yorker*:

> Purdue has continued to fight aggressively against any measures that might limit

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[206] NYAG-Purdue Settlement Agreement, Aug. 19, 2015, pg, 7-8 (emphasis added), *supra* note 81.

[207] *Id.* at pg. 15-17.

> the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's people who are dangerous."[208]

412. Further, as stated in the article, Purdue has continued to search for new users through the present, both domestically and now increasingly overseas, and in August 2015 even reportedly sought to market OxyContin to children as young as 11.[209]

C. Purdue Is Forced to Declare Bankruptcy as a Result of its False and Misleading Marketing of Opioids

413. In September of 2019, Purdue announced that it would be filing for bankruptcy as a means of resolving the thousands of opioid-related lawsuits that have been brought against it for the conduct described in this Complaint.[210] This fact alone highlights not only the validity of these claims, but the far-reaching impact of the tortious conduct. But of course, as alleged herein, Purdue did not act alone; nor will Purdue be able, alone, to remedy all of the damage that has been done.[211]

D. Cephalon's 2008 Guilty Plea for Deceptive Marketing of Actiq and Subsequent Misconduct with Successor Drug Fentora

414. Cephalon continued to engage in deceptive marketing of prescription opioids, notwithstanding Cephalon's September 2008 guilty plea to misbranding and unlawful off-label marketing of its predecessor opioid drug, Actiq, the predecessor of Fentora.[212]

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[208] Patrick Radden Keefe, The Family That Built an Empire of Pain, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[209] *Id.*
[210] *See, e.g,* Hoffman and Walsh, Purdue Pharma, Maker of OxyContin, Files for Bankruptcy (Sept. 15, 2019), https://www.nytimes.com/2019/09/15/health/purdue-pharma-bankruptcy-opioids-settlement.html.
[211] This is particularly true since it has already been discovered that the Sackler family made at least $1 billion in wire transfers abroad from Purdue. Hoffman and Walsh, *supra* note 210.
[212] *See* Guilty Plea Agreement at pg. 5, https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonguiltyplea.pdf.

415. The Department of Justice noted:

> Actiq was approved for use by opioid-tolerant patients suffering from breakthrough cancer pain, that is, patients whose cancer pain was so severe that their opioid therapies (such as morphine) were no longer effective. The label called for Actiq to be prescribed by oncologists or pain specialists familiar with opioids. Yet the defendant promoted Actiq to other doctors, including general practitioners, for more general pain uses. The use of Actiq by patients who are not yet tolerant of opioids poses particular dangers.[213]

416. The DOJ further recognized: "Cephalon had its sales representatives call on doctors who would not normally prescribe the defendant's drugs in the course of the doctor's practice. Cephalon trained its sales representatives on techniques to prompt the doctors into off-label conversations. Cephalon's compensation and bonus structure encouraged off-label marketing."[214]

417. Cephalon paid a $50 million criminal fine in connection with the plea agreement. It also paid $375 million to resolve related civil proceedings.[215] In addition to admitting guilt for "profiting" by its misbranding of Actiq, Cephalon entered into a September 2008 Corporate Integrity Agreement ("CIA") and a civil settlement with the government which included as covered conduct Cephalon's off-label marketing of Actiq between January 1, 2001 and December 31, 2006.[216]

418. The CIA required Cephalon to investigate and report all conduct which could be a probable violation of criminal, civil, or administrative laws applicable to any federal health care program and/or applicable to any legal requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized.

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[213] *See* Sentencing Memo at pg. 3, https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonsentencingmemo.pdf.
[214] *Id.* at pg. 3.
[215] *Id.* at pg. 1, 7.
[216] Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Cephalon, Inc., (Sept. 29, 2008), https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf.

419. During and after its negotiation of the Actiq guilty plea, civil settlement and CIA, Cephalon initiated and maintained an off-label marketing program for Fentora that was almost identical to the Actiq campaign for which Cephalon had pled guilty and was sanctioned, punished and prohibited from continuing.

420. Upon information and belief, Cephalon's subsequent deceptive and unlawful marketing regarding Fentora was never reported by Cephalon, as required by the CIA, thereby violating the consent decree and the CIA.

421. Since at least 2008 and up to the present, Cephalon has actively engaged in the deceptive marketing of its opioid products, despite its guilty plea and being bound by the CIA.

E. Endo's 2016 Settlement with the New York Attorney General Regarding Deceptive Marketing of Opana

422. On March 1, 2016, the NYAG entered into a settlement agreement with Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. regarding Endo's marketing and sales of Opana ER.

423. On Endo's website www.opana.com, Endo claimed until at least April 2012 that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." The NYAG found that Endo had no evidence for that statement.[217]

424. Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction." The NYAG found that those statements were unwarranted.[218]

425. Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction." The NYAG found that the "pseudoaddiction" concept has never been

[217] NYAG-Endo Settlement Agreement, March 1, 2016, at ¶ 20, *supra* note 106.
[218] *Id.* at ¶ 22.

empirically validated and has been abandoned by some of its proponents, all as alleged above.[219]

426. The NYAG also noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted . . . adverse events from marketing pamphlets."[220]

427. As part of the NYAG settlement, Endo agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive," (ii) "make statements that most patients who take opioids do not become addicted," and (iii) "use the term 'pseudoaddiction' in any training or marketing."[221]

428. Endo also paid a $200,000 penalty in connection with the settlement.[222]

429. Endo discontinued the manufacture, marketing and sale of Opana ER after the settlement.

F. Defendants Are Held Accountable for Their Roles in Fueling the Opioid Epidemic in Oklahoma

430. The Oklahoma Attorney General brought claims similar to those made here against the opioid manufactures, including Purdue, J&J, Teva, and Endo, for their role ins creating and fueling the opioid epidemic there.

431. There as here, it was alleged that they had reaped massive profits through the false and misleading marketing of opioids, causing widespread addiction and diversion, and creating a public health crisis.

432. Purdue agreed to settle the claims there for $270 million. Teva agreed to an $85

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[219] *Id.* at ¶ 23.
[220] *Id.* at ¶ 30.
[221] *Id.* at ¶ 41.
[222] *Id.* at ¶ 54.

million settlement. Endo agreed to an $8.75 million settlement.[223]

433. J&J elected for a bench trial, but after all of the evidence was heard, it was found liable for creating a public nuisance in Oklahoma and ordered to pay $465 million. This was calculated to be the cost of abating one year of the opioid crisis in Oklahoma.

G. Certain Manufacturers and Distributors Reach a Settlement Rather than Face Trial in the National Prescription Opiate Litigation

434. Thousands of state and federal lawsuits making similar allegations to those brought herein have been consolidated in a Multi-District Litigation in front of Judge Dan A. Polster in the Northern District of Ohio.[224]

435. The first two bellwether plaintiffs, Cuyahoga County, OH and Summit County, OH, were set to being trial against Manufacturers and Distributors of opioids based on the same or similar conduct alleged herein. But all of the defendants settled before trial.

436. McKesson, Cardinal, AmerisourceBergen, and Teva agreed to pay $215 million on the eve of trial.[225] Another Ohio distributor agreed to pay $1.25 million. J&J agreed to a $20 million settlement and Mallinckrodt agreed to pay $30 million.[226] As noted above, Purdue entered bankruptcy in order to avoid trial and as a means of reaching a global settlement.

V. THE DISTRIBUTOR DEFENDANTS DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS OVER THE DISTRIBUTION OF PRESCRIPTION OPIOIDS

A. The Role of Wholesale Distributors in the Pharmaceutical Supply Chain

[223] Jackie Fortier, Here's What Happened to $829 Million Oklahoma Was Awarded to Treat Opioid Addiction, (Jan. 16, 2020), https://www.kgou.org/post/here-s-what-happened-829-million-oklahoma-was-awarded-treat-opioid-addiction.
[224] MDL-2804, National Prescription Opiate Litigation, 1:17-MD-2804; https://www.ohnd.uscourts.gov/mdl-2804.
[225] Bacon and Ortiz, Drug Distributors, Opioid Maker Reach Deal with Ohio Counties in Historic Lawsuit (Oct. 21, 2019), https://www.usatoday.com/story/news/nation/2019/10/21/opioid-trial-settlement-report/4051076002/.
[226] German Lopez, Drug Companies Reach $260 Million Deal With Ohio Counties Over Role in Opioid Epidemic (Oct. 21, 2019), https://www.vox.com/policy-and-politics/2019/10/21/20924713/opioid-settlement-ohio-trial-cuyahoga-summit.

437. The Distributor Defendants are wholesale distributors of pharmaceutical drugs.

438. Pharmaceutical distributors purchase drugs directly from manufacturers and distribute them to pharmacies, hospitals, long-term care facilities, clinics, and other health care providers, essentially acting as "middlemen." Retail pharmacies and other health care providers place orders for drugs directly with the wholesale distributors who stockpile quantities of drugs in order to keep the pharmaceutical supply chain moving.

439. The Distributor Defendants operate within Pennsylvania and Clearfield County, and distribute prescription opioid drugs to pharmacies and other health care providers. As a result, the Pennsylvania Wholesale Prescription Drug Distributors License Act ("WPDDLA") requires the Distributor Defendants to register with and meet the licensing requirements of the Pennsylvania Department of Health. 63 P.S. § 391.3. The Pennsylvania Controlled Substance, Drug, Device, and Cosmetic Act ("PCSA"), 35 P.S. § 780, *et seq.*, also requires Distributor Defendants to register as distributors of controlled substances with the Commonwealth's Secretary of Health. 35 P.S. § 780-106.

440. At all relevant times, the Distributor Defendants purchased prescription opioid drugs from manufacturers, including the Manufacturer Defendants, and sold them to pharmacies and other health care providers in Pennsylvania and Clearfield County.

441. The Distributor Defendants dominate 85% of the market share for the distribution of prescription opioids. On information and belief, most or nearly all of the prescription opioids that were sold to health care providers within Pennsylvania and Clearfield County were purchased from the Distributor Defendants.

B. The Distributor Defendants' Obligations Under Pennsylvania Law and Industry Guidelines

442. While Plaintiff does not allege a cause of action under any federal statute or

regulation, Pennsylvania incorporates federal regulations and DEA interpretations for guidance with respect to its own laws and regulations.

443. The PSCA tracks and incorporates federal regulations that require the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled substances . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 35 P.S. § 780-112(c) (incorporating 21 C.F.R. § 1301.74(b)).

444. Under the relevant Pennsylvania statutes, the PSCA and WPDDLA, the Distributor Defendants are required to establish effective controls against suspicious orders to prevent prescription drugs from being diverted into the community, including:

a. Maintaining detailed records of narcotics sold to pharmacies and other retail and health care providers in order to identify and track suspicious orders;

b. Reporting suspicious orders of controlled substances, including prescription opioids, to alert regulatory and law enforcement officials when it appears that prescription drugs are being diverted for illegal use; and

c. Identifying and halting suspicious orders, based on knowledge of the legal market for narcotics, and the Distributor Defendants' unique ability to conduct due diligence.

445. The Distributor Defendants are legally required to have sufficient knowledge and understanding of the legal market for prescription narcotics and of the risks of diversion to properly control the distribution chain. To that end, the DEA instructs the Distributor Defendants and other wholesale pharmaceutical companies with respect to their responsibilities. The DEA conducts conferences to educate the Distributor Defendants and other wholesale pharmaceutical companies on the foreseeable risks of failing to properly control the distribution of controlled substances,

including prescription opioids.

446. The DEA sent the Distributor Defendants a letter on September 26, 2006 expressly stating that a distributor has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warned the Distributor Defendants that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

447. The DEA sent a second letter to the Distributor Defendants on December 27, 2007, reminding them of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (**e.g.**, "excessive purchase report" or "high unity purchase") does not met the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an ordure is suspicious may be failing to detect suspicious orders. For example, a system that identifies

> orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with the DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchase" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

448. The Healthcare Distribution Alliance, or HDMA, is the pharmaceutical distributors' trade association. The HDMA's industry compliance guidelines state that distributors are "[a]t the center of a sophisticated supply chain" and "are uniquely suited to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The HDMA's guidelines include recommended steps for the distributors' required due diligence: "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."

449. Thus, under applicable legal requirements and industry guidelines, the Distributor Defendants have an affirmative, non-delegable duty to prevent the diversion of opioid drugs into

Pennsylvania's communities. In addition to reporting suspicious orders, the Distributor Defendants are required to stop shipment on any order flagged as suspicious, and to conduct due diligence before shipping any order flagged as potentially suspicious to confirm that the order is not likely to be diverted.

450. The Distributor Defendants are, and are expected to be, a key link in the supply chain of prescription drugs. Under applicable statutes and regulations, distribution of prescription drugs should take place within a "closed system," intended to ensure that prescription drugs are sold solely for legal purposes, and not diverted for sale and use for illegal purposes. The Distributor Defendants have a duty and are expected to conduct due diligence into its prospective customers to determine whether they can be trusted to sell controlled substances only for lawful purposes.

451. The Distributor Defendants were on notice that controlled substances, including prescription opioid drugs, could be diverted for illegal purposes and sold for illegal purposes harmful to public health.

452. The Distributor Defendants knew that sales of prescription opioids increased rapidly in Pennsylvania and Clearfield County during the relevant time period, and yet continued to supply prescription opioids in dangerous quantities to retailers and health care providers.

C. The Distributor Defendants Deliberately Failed To Maintain Effective Controls Over the Distribution System In Violation of Applicable Law and Industry Guidelines

453. The Distributor Defendants deliberately failed to maintain effective control over the distribution of prescription opioids in Pennsylvania and Clearfield County in order to increase their profits from sales of the drugs. They knew that excessive amounts of prescription opioids were being distributed to pharmacies and other customers here, and that opioids were likely to be diverted for illegal and dangerous uses.

454. In a continuous pattern of ignoring red flags, the Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency in Pennsylvania and Clearfield County.

455. The Distributor Defendants supplied prescription opioids to suspicious physicians and pharmacies, allowing them to divert prescription opioids for illegal and dangerous uses.

456. The Distributor Defendants' conduct enabled the illegal diversion of opioids and resulted in the harmful effects that followed therefrom as detailed herein that has brought Pennsylvania and Clearfield County to a crisis point.

457. The Distributor Defendants have repeatedly misrepresented their compliance with their legal obligations to regulators and the public.

458. McKesson entered into a Settlement Agreement in 2008 in which it admitted failing to report suspicious orders of controlled substances to the DEA and "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to [the] DEA," but had failed in its obligations to do so. McKesson agreed to a $13.25 million civil penalty. As part of the 2008 settlement agreement, McKesson promised to no longer breach its obligations to identify and report suspicious orders of controlled substances from independent and small chain pharmacy customers. [227]

459. Despite that promise, McKesson distributed increasing amounts of prescription opioid drugs from 2008 to 2013. In January 2017, Defendant McKesson entered into another settlement agreement with the DEA, under which it paid a record $150 million fine to resolve an investigation by the U.S. Department of Justice ("DOJ").

[227] Press Release, U.S. Department of Justice, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Prescription Drugs (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

460. The 2017 agreement stated that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a)." McKesson admitted that between January 2009 and the date of the Agreement, it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson further admitted that during the same time period it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers."

461. McKesson agreed that its authority to distribute controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado would be partially suspended. McKesson reported to the SEC: "The Company expects that the suspensions will not result in a supply disruption to any customer. Customers located in the distribution center service areas described above will receive controlled substances from a different distribution center during the applicable suspension periods."[228]

462. The 2017 settlement agreement is evidence that McKesson continued to breach its duties even after the 2008 settlement. Specifically, the DOJ noted in 2017 that, although McKesson developed a compliance program after the 2008 settlement, it failed to "fully implement

[228] McKesson Corporation, Annual Report (Form 10-K) at pg. 100 (May 12, 2015).

or adhere to its own program."[229]

463. Also in 2017, Cardinal agreed to pay the State of West Virginia a $20 million fine following a criminal investigation into it's failure to report and half suspicious orders of prescription opioids.[230]

464. Defendant AmerisourceBergen paid a $16 million fine to the State of West Virginia in 2017 as the result of the same investigation into the Distributor Defendants' failure to report and block suspicious orders of prescription opioid pills.[231] AmerisourceBergen was the subject of DEA enforcement action ten years earlier when the DEA suspended the company's licenses for some of its distribution centers. In a press release on August 27, 2007, AmerisourceBergen announced the lifting of the suspension: "AmerisourceBergen Corporation today announced that on August 25, 2007 . . . the [DEA] reinstated its Orlando Distribution Center's license to distribute controlled substances. The distribution center immediately resumed shipment of controlled substances to its customers. The license was suspended in April 2007, because DEA alleged that the distribution center had not maintained effective controls against diversion of controlled substances by retail internet pharmacies. During the suspension, the Company provided the products to its customers from another distribution center. As part of the agreement leading to the reinstatement, AmerisourceBergen implemented an enhanced and more sophisticated order monitoring program in all . . . distribution centers starting July 1, 2007 . . ."[232]

465. The $16 million fine AmerisourceBergen paid to the State of West Virginia in 2017

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[229] Press Release, U.S. Department of Justice, *supra* note 216.
[230] Eric Eyre, Two Drug Distributors to Pay $36M to Settle WV Painkiller Lawsuits, Charleston Gazette-Mail (Jan. 9, 2017), https://www.wvgazettemail.com/news/health/drug-distributors-to-pay-m-to-settle-wv-painkiller-lawsuits/article_b43534bd-b020-5f56-b9f3-f74270a54c07.html.
[231] *Id.*
[232] Press Release, AmerisourceBergen Corporation, DEA Reinstates AmerisourceBergen's Orlando Distribution Center's Suspended License to Distribute Controlled Substances (Aug. 27, 2007), http://investor.amerisourcebergen.com/news-releases/news-release-details/dea-reinstates-amerisourcebergens-orlando-distribution-centers.

demonstrates that the monitoring program purportedly implemented in 2008 in order to get its licenses reinstated was ineffective. It failed utterly to prevent AmerisourceBergen from continuing to violate its legal obligations.

466. In light of the West Virginia investigation's findings and the massive fine incurred, a group of institutional investors in AmerisourceBergen urged the company to provide detailed information to its shareholders on management's plans to manage financial, legal, and reputational risks relating to the opioid crisis. AmerisourceBergen's board of directors urged shareholders to vote against the proposals which included independent board oversight and disclosure of information regarding executive pay "claw backs" for misconduct. At the board's urging, AmerisourceBergen's shareholders defeated the proposal.[233]

467. In 2019, McKesson finally settled the West Virginia lawsuit, agreeing to pay a $37 million as a result of distributing opioids to pill mills.[234]

468. Anda also agreed to pay West Virginia over $1 million to settle claims against it for distributing opioids to pill mills there.[235]

469. In 2016, Defendant Cardinal agreed to pay a $44 million fine for failure to report suspicious orders by pharmacies in three states. Cardinal's conduct violated the same federal regulations incorporated into the relevant Pennsylvania statutes. Like McKesson and AmerisourceBergen, Cardinal's multi-million dollar fine was imposed by the DOJ nearly a decade after Defendant Cardinal paid a $34 million fine to the DEA for failure to report suspicious orders

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[233] Eric Eyre, AmerisourceBergen Shareholders Reject Proposals Related to Opioid Crisis, Charleston Gazette-Mail (March 1, 2018), https://www.wvgazettemail.com/news/health/wv_drug_abuse/amerisourcebergen-shareholders-reject-proposals-related-to-opioid-crisis/article_cd0fb615-b87f-5daf-bd85-080d1caf947c.html.

[234] West Virginia Officials Announce Record Settlement with Drug Distributor (May 3. 2019), https://www.wtap.com/content/news/West-Virginina-officials-announce-record-settlement-with-drug-distributor-509378811.html.

[235] *Id.*

of opioids.[236]

470. A recent report revealed the level of Walmart's efforts to avoid liability for its failure to prevent diversion in Texas. Extensive lobbying allegedly allowed them to evade both civil and criminal indictments related to opioid dispensing in the Eastern District of Texas.[237]

471. As substantial as those fines have been, they pale in comparison to the many billions of dollars in revenue the Distributor Defendants continue to receive from opioid sales, and have not caused the Distributor Defendants to change their conduct. Instead, the Distributor Defendants still supply quantities of prescription opioids in Pennsylvania and Clearfield County that far exceed what could be consumed for medically necessary purposes, especially given that each Defendant knows that it is not the only opioid distributor profiting on a large scale from prescription opioid sales.

D. The Distributor Defendants Misrepresented Their Compliance With Their Legal Obligations

472. The Distributor Defendants held themselves out to the public as law abiding wholesale drug distribution companies, even though they were not in compliance with their legal obligations, including those imposed by Pennsylvania licensing regulations.

473. The purpose of this deception was to convince the public that the Distributor Defendants were fighting the opioid epidemic in partnership with governments and public health officials.

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[236] Press Release, U.S. Department of Justice, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[237] Jessica Eisinger and James Bandler, Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment, ProPublica (Mar. 25, 2020) ("Before the Texas prosecutors could file their case, however, Walmart escalated concerns to high-ranking officials at the DOJ, who then intervened. Brown was ordered to stand down. On Aug. 31, 2018, Trump officials officially informed Walmart that the DOJ would decline to prosecute the company . . . ."), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

474. The Distributor Defendants represented in public filings with the U.S. Securities & Exchange Commission that they were in compliance with legal requirements in the years leading up to the multi-million fines they paid in 2016 and 2017.

475. In 2012, for example, AmerisourceBergen Corporation stated in its 10-K with respect to Defendant AmerisourceBergen Drug Corporation: "Wholesale distributors of controlled substances must hold valid DEA licenses, meet various security and operating standards and comply with regulations governing the sale, marketing, packaging, holding and distribution of controlled substances. The DEA, FDA and state regulatory authorities have broad enforcement powers, including the ability to suspend our distribution centers from distributing controlled substances, seize or recall products and impose significant criminal, civil and administrative sanctions. We have all necessary licenses or other regulatory approvals and believe that we are in compliance with all applicable pharmaceutical wholesale distribution requirements needed to conduct our operations."[238]

476. Also in 2012, McKesson informed its investors: "Certain of our businesses may be required to register for permits and/or licenses with, and comply with operating and security standards of the DEA , . . . various state boards of pharmacy, . . . and/or comparable state agencies . . . As part of these operating, security and licensure standards, we regularly receive requests for information and occasionally subpoenas from government authorities. Although we believe that we are in compliance in all material respects with applicable laws and regulations, there can be no assurance that a regulatory agency or tribunal would not reach a different conclusion concerning the compliance of our operations with applicable laws and regulations."[239]

477. Defendant Cardinal disclosed that the West Virginia Attorney General alleged that Cardinal "failed to maintain effective controls to guard against diversion of controlled substances

[238] AmerisourceBergen Corporation, Annual Report (Form 10-K), at 12 (Nov. 27, 2012).
[239] McKesson Corporation, Annual Report (Form 10-K), at 16 (May 2, 2012).

in West Virginia, failed to report suspicious orders of controlled substances . . . and were negligent in distributing controlled substances to pharmacies that serve individuals who abuse controlled substances." Cardinal further stated that the company was "vigorously defending ourselves in this matter."[240]

478. After the Distributor Defendants made public statements misrepresenting their compliance with applicable laws and regulations, each entered into one or more settlement agreements with federal and state law enforcement authorities pursuant to which they paid tens of millions of dollars in fines for failing to identify and block suspicious orders of prescription opioid pills.

479. The Distributor Defendants made other public statements misrepresenting the effectiveness of their monitoring and compliance systems. For example, in an interview with the Washington Post, an executive from Defendant Cardinal claimed that the company uses "advanced analytics" to monitor its supply chain, and represented that it was "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[241]

480. Cardinal's sales volumes and history of violations demonstrate that the executive either misrepresented this "advanced analytics" system, or Cardinal ignored the results of the system in order to maximize profits.

481. Former CEO and Chairman of Cardinal, George Barrett, then the Executive Chairman of Cardinal's Board of Directors, testified before a committee of the U.S. House of Representatives on May 8, 2018 that Cardinal provided a "secure channel" to deliver prescription

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[240] Cardinal Health, Inc., Annual Report (Form 10-K), at 62 (Aug. 13, 2015).

[241] Lenny Bernstein, et al., How Drugs Intended For Patients Ended Up In the Hands of Illegal Users: 'No One Was Doing Their Job', Washington Post (Oct. 22, 2016), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.751b039805c9.

medications aided by a "constantly adaptive and rigorous system to combat controlled substance diversion."[242]

482. In the same hearing, the Chairman, President, and CEO of AmerisourceBergen Corporation testified that AmerisourceBergen "has had in place a system to monitor the orders it receives" since at least the 1980s, and represented through a detailed step-by-step description that the company has fully implemented and adhered to its own system.[243]

483. John Hammergren, Chairman, President, and Chief Executive Officer of McKesson, testified about his company's "cutting-edge controlled substances threshold management program," that purports to identify suspicious orders and report blocked orders to federal and state authorities.[244]

484. McKesson also stated publicly in 2016 that it had a "best-in-class controlled substance monitoring program to help identify suspicious orders," and that the company is "deeply passionate about curbing the opioid epidemic in our country."[245] Like Cardinal, McKesson's history of violations and sales figures show the statement was intentionally deceptive, or

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[242] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 2, 4 (2018)(statement of George S. Barrett, Executive Chairman, Board of Directors, Cardinal Health, Inc.).

[243] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 2, 4 (2018)(statement of Steven H. Collis, Chairman, President, and Chief Executive Officer, AmerisourceBergen Corporation) at pg. 7-9, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf).

[244] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 2, 4 (2018)(statement of John Hammergren, Chairman, President, and Chief Executive Officer, McKesson Corporation) at pg. 6, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-HammergrenJ-20180508.pdf).

[245] Scott Higham, *et al.*, Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Washington Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.29838a59f594.

McKesson ignored the system's warnings.

485. The Distributor Defendants misled the public by intentionally concealing facts that would prove the District Attorney's claims asserted here.

486. Meanwhile, the DEA's enforcement actions have been insufficient to deter the Distributor Defendants from their wrongful conduct. On information and belief, the Distributor Defendants hold multiple DEA registration numbers. When one facility is suspended, the Distributor Defendants ship controlled substances from another facility.[246]

487. The Distributor Defendants continue to fail to report or prevent the shipment of suspicious orders of prescription opioids, or otherwise take action to prevent the diversion of prescription opioids for illegal and dangerous purposes in Clearfield County.

488. The Distributor Defendants' deceptive conduct has caused and contributed to the opioid crisis in Clearfield County by creating, enabling, and fueling a secondary market for prescription opioids.

489. The Distributors' false, deceptive and/or misleading statements and practices are a direct violation of the UTPCPL.

VI. PHARMACY DEFENDANTS ARE LIABLE FOR THE FAILURE TO CONTROL OPIOIDS IN THEIR CAPACITIES AS BOTH DISTRIBUTORS AND RETAILERS

490. The Pharmacy Defendants, Walmart, CVS, Rite Aid, Giant Eagle, and Giant/Martin's, operate retail pharmacies that dispense opioids in Pennsylvania and Clearfield County.

491. These retail pharmacies operate a dual role in the distribution chain of prescription

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[246] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion*, Hearings before the Subcommittee Oversight and Investigations, 115th Cong. (2018) (Statement of Representative Gus Bilirakis) at pg. 5, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.

medicines because, in addition to dispensing, they also self-distribute certain prescriptions to their own stores.

492. At the same time, retail pharmacies also utilize other distributors for certain medications, often entering into exclusive contracts with a distributor.

493. During times material to this Complaint, the Pharmacy Defendants acted as both Distributors and Retailers of opioids within Clearfield County.

494. As Distributors, the Pharmacy Defendants are liable just the other Distributor for the failure of their common law duty to monitor, report, investigate and halt suspicious orders, as described in detail, *supra,* § V.

495. As Retailers, the pharmacies had a duty, at the corporate and pharmacy level, to enact policies and procedures for dispensing opioids in a reasonable and safe manner that would not lead to addiction and diversion.

496. Pursuant to the Federal CSA, PACSA, and the WPDDLA, Defendants are required to establish effective controls to defeat and prevent suspicious orders of opioids from being filled and the diversion of drugs into the community.

497. As Retailers, the Pharmacy Defendants violated their statutory and common law duties to act with reasonable care in the sale of these inherently dangerous prescription drugs. Instead of taking any meaningful action to stem the flow of opioids, they continued to participate in the oversupply and profit from it.

498. They had a duty to provide effective controls and procedures to guard against diversion from their retail activities, yet contrary to this they dispensed substantial quantities of opioids in Clearfield County that were diverted.

499. Pharmacy Defendants were aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and

dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids, they continued to participate in the oversupply and profit from it.

500. As part of their retail business, Pharmacy Defendants developed significant data regarding patterns and instances of improper distribution and prescribing, but rather than utilize this date to combat diversion, they provided it to other Defendants in exchange for rebates and other considerations. In doing so they ignored signs at the retail pharmacy level that they knew or should have known were indicative of diversion within Clearfield County, causing substantial harm therein.

501. As Retailers, the Pharmacy Defendants also developed metrics, quotas, and bonus structures that they utilized for purposes of retailing opioids, all of which exacerbated the violations of their duties and the diversion of opioids. These metrics and quotas made it nearly impossible for individual pharmacists to comply with applicable laws and regulations, while also creating a greater number of dispensing errors.

502. The Pharmacy Defendants also failed to act in accordance with the duty required by a responsible retailer of dangerous drugs by failing to perform due diligence with respect to opioid orders, failing to ensure that employees were exercising reasonable care, failing to adequately train employees to detect diversion, failing to identify problem prescribers, failing to analyze their own demographic data for indicators of diversion, failing to conduct internal and external audits, and failing to address employee concerns regarding opioid prescriptions, among others.

503. At a corporate level, these Defendants failed to put procedures and policies in place that were necessary to comply with their legal duties.

504. The Pharmacy Defendants have also misrepresented their compliance with their statutory and common law duties and/or made false and misleading statements regarding their

suspicious order monitoring programs, their efforts to prevent diversion and cooperate with law enforcement, and their actions take to combat addiction and the opioid epidemic.

505. These Defendants have also tried to shift the blame from themselves onto the physicians and other healthcare providers who wrote prescriptions, while ignoring or failing to admit that, had they actually complied with their legal duties to detect and prevent diversion, rather than just falsely and misleadingly claiming to do so, these pills would not have been dispensed.[247]

506. All of these actions resulted in increased addiction to and diversion of opioids in Clearfield County, which has significantly contributed to the opioid epidemic and the resultant harms, as described in this Complaint.

507. All of the foregoing actions and/or inactions, by the Pharmacies as retailers, arise from the negligence of the Pharmacy Defendants themselves; it is not alleged that they arise from professional negligence on the part of individual pharmacists.

508. The Pharmacy Defendants' false, deceptive and/or misleading statements and practices are a direct violation of the UTPCPL.

VII. THE CIVIL CONSPIRACY AMONG DEFENDANTS

A. Conspiracy Among Manufacturer Defendants

509. Manufacturer Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors, through misrepresentations and omissions regarding the appropriate uses, risks, and safely of opioids, to increase sales, revenue, and profit from their opioid products.

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[247] *See, e.g.,* Joanne Finnegan, Major Chains Including CVS, Walmart Say Physicians- Not Pharmacists- Responsible for Fueling Opioid Crisis, FierceHealthcare (Jan. 8, 2020), https://www.fiercehealthcare.com/practices/major-pharmacy-chains-file-lawsuits-saying-physicians-not-pharmacists-are-responsible.

510. This interconnected and interrelated network relied on the Manufacturer Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMBs, patient education materials, and Front Groups developed and funded collectively by the Manufacturer Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

511. Manufacturer Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of the false proposition identified *supra,* §§ II-III.

512. The Manufacturer Defendants knew that none of these propositions was true and that there was no evidence to support them.

513. Each Manufacturer Defendant worked individually and collectively to develop and actively promote their false propositions in order to mislead physicians, patients, health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

514. The Manufacturer Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers of the safety of opioids, and to hide their actual risk and dangers. In doing so, the Manufacturer Defendants effectively built a new and extremely lucrative opioid marketplace for their own select group of industry players.

515. Manufacturers promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to meet for a single or even a handful of individual members.

516. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Manufacturer Defendant to expand its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other

Manufacturer Defendants.

517. Their conspiracy utilized startling tactics, such as their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective, unbiased, and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction. Instead, Manufacturers worked together to fabricate an entire universe of misinformation, paid experts, and Front Groups to legitimize, cite, to, and create more of that misinformation, used legally mandated medical education as a platform to spread and reinforce their misinformation, and then collected massive quantities of data to target for special attention those prescribers who were not playing along. All of which was done to create wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Manufacturer Defendants were able to create the illusion of consensus through their materials and sham references.

518. All of the foregoing was done in furtherance of the conspiracy.

B. Conspiracy Among All Defendants

519. At a broader level, all Defendants took advantage of and advanced the industry structure created by Manufacturers, including avoiding internal checks and balances, to their collective advantage. Fundamentally, all Defendants worked together to further the misinformation about opioids and increase the oversupply of these dangerous drugs in order to maximize their profits.

520. All Defendants agreed to work to increase the supply of opioids by fraudulently increasing the quotas that governed both the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from opioids. None of the Defendants took any action to counteract these increases or to call attention to the danger they created.

521. The interaction and length of the relationships between and among the Defendants

reflects a deep level of interaction and cooperation between and among Defendants, all of whom operate in a "closed system" of opioid manufacturing, distribution, and sale. The Manufacturers, Distributors, and Pharmacies were not operating in isolation; rather they worked together as a united entity, on multiple fronts such as marketing, detailing of physicians, creation of industry guidelines, sharing of proprietary information, lobbying politicians, and coordinated tactics to avoid creating suspicious orders and/or red flags, all with the single goal of boosting their profits from prescription opioids.

522. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in a number of ways, including, for example, membership in industry groups like the HDA.

523. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties to monitor, report, investigate, and halt suspicious orders. The Defendants overwhelmingly agreed on the same approach - to fail to identify, report or halt suspicious opioid orders, which naturally lead to diversion.

524. Defendants' agreement to restrict reporting provided an added layer of insulation from legal scrutiny for the entire industry as Defendants were, thanks to their own significant lobbying and policy efforts, collectively responsible for each other's compliance through their reporting obligations.

525. Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from Defendants facilities. They knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders or maintain controls against diversion could be brought to the attention of state and federal authorities. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with authorities.

526. Defendants refusals to report suspicious orders also allowed them to keep quotas artificially high, since it meant that the authorities had no basis for lowering or even refusing to increase production quotas due to diversion. This conspiracy achieved the collective end goal: providing Defendants blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids to the market they created. The consequences of this for the citizens of this Commonwealth and Clearfield County have been catastrophic.

527. For instance, Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's opioid at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, the distributor requests a chargeback from the manufacturer and, in exchange for the payment. the distributor identifies the product, volume, and the pharmacy to which it sold the product.

528. Upon information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. The information exchange that accompanies these chargebacks means that the Distributors provide the Manufacturer with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The Manufacturer Defendants used this information to create high-level analysis of overall distribution and direct the Distributor Defendants on how to most effectively sell their prescription opioids.

529. While highly profitable, this practice of chargebacks and rebates was blatantly illegal. Pennsylvania law, which incorporates federal regulations, is clear: just like opioid distributors, opioid manufacturers required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion."

35 Pa. C.S.A. § 780-ll2(c), via 21 C.F.R. § 1301.74; 21 USCA § 823(a)(l). Instead of using the data they collected to fulfil this duty, they chose to use it to increase their profits with a blatant disregard to the harm that it caused.

530. The Department of Justice confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failing to report suspicious orders of controlled substances, including opioids, and for violating rccord keeping requirements. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt:

> did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere . . . . Mallinckrodt's actions and omissions form a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street . . . Manufacturers and distributors have a critical responsibility to ensure that controlled substances do not get into the wrong hands . . . . [248]

531. Mallinckrodt entered into a Memorandum of Agreement ("2017 Mallinckrodt MOA"') which acknowledges that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[249]

532. This MOA specifically instructed Mallinckrodt to monitor and report suspicious orders from the downstream customers to distributors and to use its chargeback data to accomplish this. Included was a command that Mallinckrodt prevent a recurrence of diversion by downstream

[248] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

[249] *See* https://www.justice.gov/usao-edmi/press-release/file/986026/download

customers.[250]

533. Like Mallinckrodt, all Manufacturers and Distributors had a duty to monitor, investigate, report and halt suspicious orders and to use all the tools at their disposal to do so. Instead, they chose to work in combination to use these tools to enhance their profits.

534. The Pharmacy Defendants also had this same exact duty with respect to their Distribution practices. But they were uniquely responsible, at both the corporate and pharmacy level, for creating policies and oversight that would prevent diversion and abuse of opioids from their retail stores.

535. But even in the instances when Defendants actually put suspicious order monitoring systems in place, the Distributors and Pharmacies also conspired to avoid and undermine them completely. For instance, upon information and belief, if a pharmacy order exceeded a Distributors' threshold such that it would trigger a red flag (which must be reported to the DEA and halted until the Distributor investigates it to determine the potential for diversion), Distributors would either override the threshold or split the order up among different distribution facilities such that these smaller orders did not exceed the threshold and trigger a red flag.

536. The Defendants have, therefore, further enabled the supply of prescription opioids to what they knew or should have known were suspicious physicians and/or pharmacies, which enabled the diversion of opioids, aided criminal activity, and resulted in the explosion of large quantities of opioids into an illegal secondary market.

537. At the same time, all of the Defendants have misrepresented their compliance with Pennsylvania and federal law.

538. The Manufacturers, Distributors, and Pharmacies have not undertaken the conduct

[250] 2017 Mallinckrodt MOA, at pp. 2-3.

and practices described herein in isolation, but rather as part of a common scheme or conspiracy. They collectively breached their respective duties with respect to monitoring suspicious orders of opioids and preventing diversion in order to maximize their profits, minimize governmental interference, and increase the sale of prescription opioids.

539. Defendants also utilized their interpersonal relationships and communication networks to further their goals through contractual relationships, information sharing, and other coordinated activities.

540. For instance, Defendants utilized vault security programs to further their goals. Each of the defendant is required to maintain certain security protocols and storage facilities for the distribution and sale of opioids. Upon information and belief, Defendants negotiated agreements whereby Manufacturer Defendants installed security vaults for other Defendants in exchange for agreements to maintain minimum sales performance thresholds. Upon information and belief, not only did these minimum thresholds present a contradiction with respect to reporting suspicious orders, but the agreements were also a tool used to avoid reporting requirements.

541. Distributor Defendants also developed "know your customer'" questionnaires and files that, upon information and belief, were used to provide other Defendants with information that helped them sell more opioids. This information included the number of pills that certain pharmacies sold; how many noncontrolled substances were sold compared to controlled substances; whether the pharmacy buys from other distributors; and the types of medical providers in the area including pain clinics, general practitioners, hospice facilities, and cancer treatment facilities. These questionnaires would have certainly made the recipients aware of suspicious orders.

542. Finally, Defendants furthered their goals and their conspiracy through joint participation in lobbying groups and trade industry organizations, including the Pain Care Forum

and the HAD (formerly HDMA).

543. The Pain Care Forum ("PCF") is a collation of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF shaped public policy regarding the use of prescription opioids for more than a decade.

544. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse." Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including making it more difficult for the DEA to stop suspicious orders of opioids.[251]

545. All of the Defendants stood to profit from lobbying in favor of prescription opioid use. It is not surprising, therefore, that they have all been members and/or participants in the PCF, which has been lobbying on behalf of all of the Defendants for more than a decade. In 2012, the PCF's membership and participating organizations included the HOA (of which Defendants are members)) Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), and Teva (the parent company of Cephalon). On information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

546. Through the PCF and other organizations, the Defendants worked together to achieve their common purpose of violating laws designed to protect against diversion in order to ensure the continued unfettered sale of opioids. Defendants took numerous steps in furtherance of their conspiracy, including failing to monitor, report, and halt suspicious orders; identifying suspicious orders but filling them regardless without reporting them, knowing that they were suspicious and/or being diverted to the illicit drug market; misleadingly withholding information

[251] Mathew Perrone, Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic, The Center for Public Integrity (9/19/16, updated 12/15/16), https://publicintegrity.org/politics/state-politics/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic/

regarding suspicious orders and diversion from state authorities (both regarding their own orders and those of other Defendants); and making false statements to authorities, the public, and others regarding their compliance with state and federal laws that were aimed at controlling diversion.

547. Based on the foregoing, all of the Defendants are co-conspirators and are, therefore, equally liable for one another's actions and violations of the law.

VIII. DEFENDANTS' MARKETING, DISTRIBUTION, AND DISPENSING OF OPIOIDS HAS CAUSED AN OPIOID EPIDEMIC THROUGHOUT THE NATION AND IN CLEARFIELD COUNTY

A. The National Prescription Opioid Epidemic

548. The United States and Clearfield County are suffering from an epidemic of addiction to opioids that continues to expand at an alarming rate. It is now the worst drug epidemic in our nation's history.

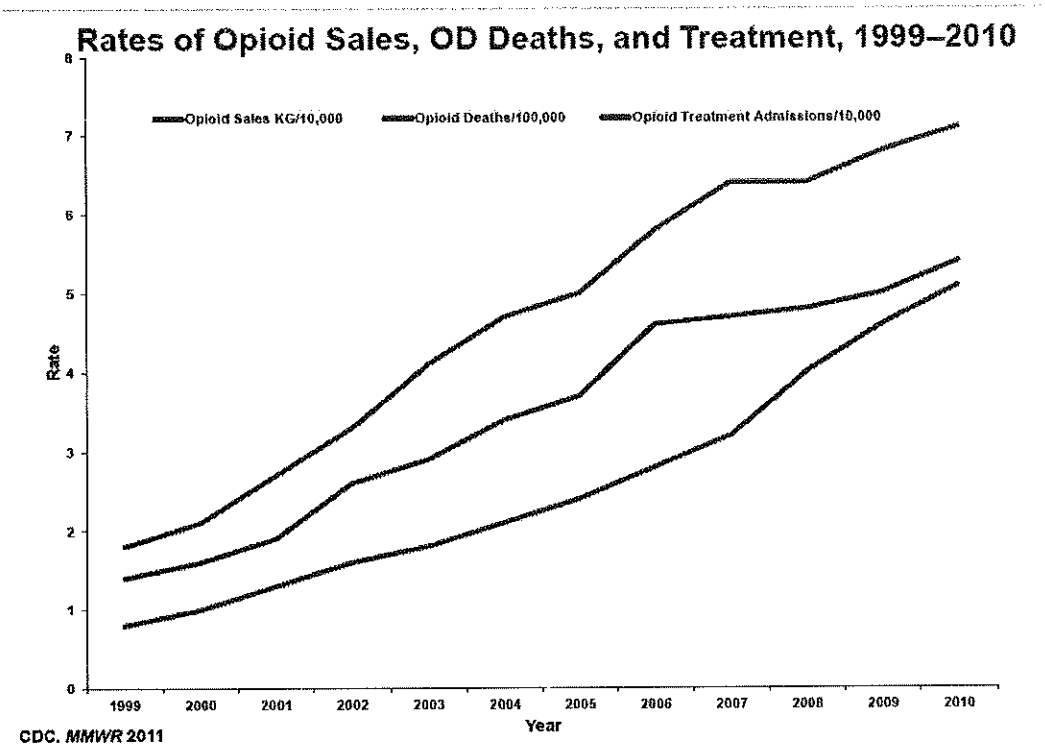
549. Starting in or about 1996 – and coinciding with a rapid increase in prescription opioid use for medical purposes as more fully set forth herein – the United States has experienced an opioid epidemic unlike any other before. In the public health community, an epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discrete period of time.[252] The principal disease associated with the opioid epidemic is opioid addiction, also known as opioid use disorder.

550. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable. Unfortunately, for a variety of reasons, including a shortage of and limitations on private and public resources, the presence of shame and stigma, and the presence of barriers to treatment, only a small percentage of patients who need treatment actually receive the right types

[252] Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics (2017), https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section11.html.

of treatment and levels of care, in the right settings, for the right lengths of time. In the absence of proper treatment, the disease of addiction is progressive and, all too often, fatal.

551. In 2011, the CDC published an analysis of opioid use from 1999-2010 which indicated a sharp increase nationally in the prevalence of opioid addiction and opioid use disorder. The study found a 900% increase in opioid users seeking treatment for opioid addiction in the period 1999-2010. As reflected in the following graph, the sharp increase in opioid addiction during this period has also led to a sharp increase in both fatal and non-fatal opioid overdoses, as well as other opioid-related adverse health effects:[253]



552. In the period 1999-2014, the CDC estimated that there were 165,000 overdose

[253] Andrew Kolodny, M.D., Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction, at 23 (2016), http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf; Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008, CDC (Nov. 4, 2011) (similar graph), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm.

deaths in the United States associated with prescription opioid use.[254] Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.[255] Thus, in the period 1999-2014, an estimated 5 million non-fatal opioid overdoses occurred.

553. The CDC has acknowledged the presence of an "opioid epidemic," also referred to as an "opioid overdose epidemic."[256] Similarly, a 2017 report by the U.S. Drug Enforcement Agency noted that the "opioid overdose crisis . . . is a public health and public safety emergency."[257] The U.S. Department of Health and Human Services recognized the existence of an "opioid crisis" and stated that the "United States is in the midst of a prescription opioid overdose epidemic."[258]

554. The U.S. Surgeon General also noted in 2016 that opioid use has led to an "urgent health crisis" that specifically coincided with "heavy marketing of opioids to doctors."[259] Similarly, the National Institutes of Health identified the drug industry's "aggressive marketing" as a major cause of the opioid epidemic: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the

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254 CDC Guideline, March 18, 2016, at pg. 2, 18, *supra* note 14.

255 Andrea Hsu, Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests, NPR (Aug. 22, 2017), http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

256 CDC Guideline, March 18, 2016, at pg. 3, 34, *supra* note 14; *accord* CDC Press Release, CDC Launches Campaign to Help States Fight Prescription Opioid Epidemic (Sept. 25, 2017), https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html (recognizing "opioid epidemic").

257 Analysis of Overdose Deaths in Pennsylvania, 2016, Drug Enforcement Agency Philadelphia Division and the University of Pittsburgh, at pg. 5 (July 2017) (hereinafter "*Analysis of Overdose Deaths in Pennsylvania,* July 2017"), https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf.

258 Opioids: The Prescription Drug & Heroin Overdose Epidemic, U.S. Dept. of Health and Human Services (2017), https://www.hhs.gov/opioids.

259 Opioid Crisis Message from the US General Surgeon General, (Aug. 2016), https://amersa.org/opioid-crisis-message-from-the-us-surgeon-general/ (emphasis added).

number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[260]

555. On October 26, 2017, the President of the United States declared a "public health emergency" caused by opioid addiction.[261] The action allows for shifting of resources within certain government programs to help people eligible for those programs receive treatment for opioid addiction and use disorder.[262]

556. On January 10, 2018, Pennsylvania Governor Tom Wolf declared the opioid (and heroin) epidemic in Pennsylvania to be a statewide disaster and public health emergency. This declaration has been repeatedly renewed since that time.

B. Increases in Prescription Opioid Sales by Defendants As a Result of their False and Deceptive Marketing Were a Substantial Factor in the Current National Opioid Epidemic

557. As reflected above, over the past two decades, the rates of prescription opioid sales, opioid addiction, and opioid overdose deaths have risen together and closely track each other.

558. In 2017, the CDC noted that "[p]rescription opioid-related overdose deaths and admissions for treatment of opioid use disorder have increased in parallel with increases in opioids prescribed in the United States, which quadrupled from 1999 to 2010."[263] Similarly, it noted in 2016 that "[s]ales of opioid pain medication have increased in parallel with opioid-related overdose

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[260] America's Addiction to Opioids: Heroin and Prescription Drug Abuse (2014) (emphasis added), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[261] White House Office of the Press Secretary, President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis (Oct. 26, 2017), https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis; *see also* The President's Commission on Combating Drug Addiction and the Opioid Crisis (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[262] *Id.*

[263] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, at pg. 1 (July 7, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6626a4.pdf.

deaths."[264]

559. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the unprecedented increase in the use of prescription opioids for medical purposes substantially contributed to both opioid epidemics in the period 1999-2014.[265] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated these data with data relating to admissions for treatment of opioid use disorders and overdose deaths.

560. As can be seen from the graph *supra,* which correlates prescription opioid addiction and overdoses starting in 1999, sharp, dramatic increases in the sale of prescription opioids for medical purposes closely track sharp, substantial increases in addiction as measured by treatment admissions (as previously described) and fatal overdoses.[266]

561. Using the above data and analysis, the CDC and other researchers have concluded that the increase in prescriptions of opioid drugs for daily use to treat chronic pain substantially contributed to the epidemics in opioid addiction and overdoses.[267]

562. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin. Apparently, as law enforcement and public health authorities and the medical profession have begun to limit the improper use of prescription opioids and for other reasons (including the high price of prescription opioids), which have reduced the supply of prescription opioids for legal

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264 CDC Guideline, March 18, 2016, at pg. 2, *supra* note 14.
265 *Id.* at pg. 2.
266 Kolodny, Jan. 12, 2015, at 560, *supra* note 12.
267 CDC Guideline, March 18, 2016, at 2, *supra* note 14.

use, many prescription opioid users suffering from opioid addiction have turned to heroin available on the black market.[268]

563. Based on the growing weight of scientific evidence, public health experts have concluded that the current opioid epidemics of addiction and overdoses have been caused primarily by opioid pain relievers marketed, distributed, and sold by Defendants and others for long-term daily use to treat chronic pain. Studies show that the vast majority of patients who die from an overdose were first exposed through prescription opioids.[269]

564. The CDC has concluded that unless and until the prescription of opioids by the medical community is reduced to appropriate levels, the current epidemics of opioid addiction and overdoses will not be contained.[270] Even then, it may take decades before the populations addicted as a result of the current opioid epidemic to be appropriately treated.

565. Chronic pain patients and others – from the users to their loved ones and communities at large – have been devastated by the prescription and use of opioids for medical uses. Some estimates of long-term prescription opioid users developing addiction are frighteningly high: one study found that between 30% and 40% of all long-term users of opioids experience problems with opioid use disorders.[271] According to the CDC, *128 Americans die every day from an opioid overdose.*[272]

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[268] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. *See* Kolodny, Jan. 12, 2015, at 560, *supra* note 12.

[269] Kolodny, Jan. 12, 2015, at pg. 563, *supra* note 12; CDC Guideline, March 18, 2016, at 2, *supra* note 14.

[270] Kolodny, Jan. 12, 2015, at pg. 565, *supra* note 12; CDC Guideline, March 18, 2016, at 2, *supra* note 14.

[271] J. Boscarino *et al.*, Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011); J. Boscarino *et al.*, Risk Factors for Drug Dependence Among Outpatients on Opioid Therapy in a Large US Healthcare System, 105(10) Addiction 1776 (2010).

[272] Opioid Overdose, Understanding the Epidemic, Centers for Disease Control and Prevention, (2020), https://www.cdc.gov/drugoverdose/epidemic/index.html

566. The opioid epidemic has led to many more overdose deaths than the heroin epidemic of the 1970s and crack cocaine epidemic of the 1980s and 1990s, prompting public health officials and commentators to conclude that the current opioid epidemic is the worst drug epidemic in U.S. history, worse than the previous heroin and crack cocaine epidemics combined.[273]

567. The prescription opioid epidemic has devastated communities like Clearfield County, where the costs are shared by individuals who have never taken opioids. Infants are born addicted to opioids. Children have lost parents. Adults have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. Employers have lost healthy and productive workers. Patients are paying more for health care while health care providers suffer economic losses for increased costs. Illegal drug-dealing and drug-related crimes have depleted court and law enforcement resources, and made neighborhoods less safe. First responders have had to deal with overdoses and have not been able to respond to other emergencies, at times, as a result. Addicts using and seeking opioids have overtaken parks, libraries and other spaces meant for public use and enjoyment. Homelessness and poverty have increased, along with the attendant social costs. By any metric, the opioid epidemic has been detrimental to the quality of life, both nationally and in Clearfield County.

568. According to the White House Council of Economic Advisers (CEA), it is estimated that the opioid epidemic cost $696 billion in 2018—or 3.4 percent of GDP—and *more*

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[273] Andrew Kolodny, M.D., Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction, at pg. 4 (2016), http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf.

than $2.5 trillion for the four-year period from 2015 to 2018.[274]

C. Pennsylvania's Opioid Epidemic

569. Pennsylvania has been particularly impacted by the national opioid epidemic. It has been among the top four states with the highest opioid use and overdose rates and, in 2016, nearly thirteen people died per day from a drug overdose in this Commonwealth.[275] The rate of drug-related overdoses here exceeds the national average.

570. Between 1999 and 2017, opioids killed an estimated 26,300 Pennsylvanians. From 2015 to 2017, Pennsylvanians survived more than 6,400 opioid overdoses.[276]

571. The opioid epidemic continues to ravage communities across the Commonwealth. For example, in 2018 Pennsylvania coroners and medical examiners reported 4,491 drug-related overdose deaths and between 2015 and 2018, and there was a 36% increase in the number of drug-related overdose deaths in Pennsylvania.[277] Over half of those deaths involved opioids of which nearly a quarter were prescribed.[278] Oxycodone is the most frequently reported prescription opioid in toxicology testing of drug-related overdose decedents in Pennsylvania.[279]

572. Thousands of patients who took prescription opioids in Pennsylvania have became addicted and died. Drug overdoses skyrocketed 81% in 2016 alone and in 2017 Pennsylvania suffered more drug overdose deaths than any other state; a majority of those deaths were caused

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[274] The Full Cost of the Opioid Crisis: $2.5 Trillion Over Four Years, (2019), Council of Economic Advisors, https://www.whitehouse.gov/articles/full-cost-opioid-crisis-2-5-trillion-four-years/ (emphasis added).
[275] Pennsylvania Department of Drug and Alcohol Programs, Opioid and Prescription Drug Monitoring Program, https://www.health.pa.gov/topics/Documents/Health%20Planning/11-SHA-Opioids-and-PDMP_2-18.pdf.
[276] The Pa. Counties Where Police Have Most Used the Overdose Antidote Narcan, Lehigh Valley Live (May 17, 2019), https://www.lehighvalleylive.com/news/2018/03/where_pa_police_are_using_narc.html.
[277] Overdose Free PA, Death Data Overview, https://www.overdosefreepa.pitt.edu/know-the-facts/death-data-overview/.
[278] Pennsylvania DEA Opioid Threat Report 2018.
[279] *Id.*

by opioids.[280]

573. Nor has this crisis abated significantly in Pennsylvania. From January 1, 2018 to January 25, 2020, 31,610 doses of naloxone where administered by EMS in Pennsylvania and there were 21,011 visits to the ER for opioid overdoses. From January 1, 2018 to December 31, 2019, there were 3,705 new cases of neonatal abstinence syndrome ("NAS").[281]

574. Despite these fatalities, opioid use in Pennsylvania remains one of the highest rates in the country.

575. As the number of opioid-related overdoses continues to rise in Pennsylvania and nationwide, the economic cost of the epidemic has skyrocketed in recent years. From health care spending to addiction treatment and from lost productivity to criminal justice expenses, the financial impact of these costs is staggering. Between 2012 and 2016, opioid-related fatalities in Pennsylvania cost taxpayers more than $142 billion dollars. These costs more than doubled from 2015 to 2016.[282] These figures reflect only four years of this much longer epidemic.

576. U.S. Senator Bob Casey released a report concluding that the opioid crisis cost Pennsylvania over $50 billion in 2016 alone.[283]

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[280] Jessica Glenza, Opioid Crisis: Overdoses Increased by a Third Across US in 14 Months, Says CDC, The Guardian (2018), https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc; Eric Durkin, US Drug Overdose Deaths Rose to Records 72,000 Last Year, Data Reveals, The Guardian (2018), https://www.theguardian.com/us-news/2018/aug/16/us-drug-overdose-deaths-opioids-fentanyl-cdc; Lenny Bernstein, Bloomberg Philanthropies Will Donate $50 Million to Battle Opioid Epidemic, The Washington Post (2018), https://www.washingtonpost.com/national/health-science/bloomberg-philanthropies-will-donate-50-million-to-battle-opioid-epidemic/2018/11/29/14fccc5c-f3fb-11e8-80d0-f7e1948d55f4-story.html; Pennsylvania DEA Opioid Threat Report 2018.

[281] Pennsylvania DEA Opioid Threat Report 2018, at 35, https://www.dea.gov/sites/default/files/2018-10/PA%20Opioid%20Report%20Final%20FINAL.pdf

[282] Report from U.S. Senate Committee on Health, Education, Labor, and Pensions, The Economic Cost of the Opioid Epidemic in Pennsylvania, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2018/10/The-Economic-Cost-of-the-Opioid-Epidemic-in-Pennsylvania.pdf

[283] Casey Unveils New Analysis Showing Economic Impact of Opioid Crisis in Pennsylvania, (2018), https://www.casey.senate.gov/newsroom/releases/casey-unveils-new-analysis-showing-economic-impact-of-opioid-crisis-in-pennsylvania.

D. Clearfield County's Opioid Epidemic

577. Clearfield County is now engulfed in the opioid epidemic created by Defendants, which has led to a public health and safety crisis of an unprecedented and disastrous nature. The current epidemic is directly attributable to the Defendants' false, misleading, deceptive, and improper marketing, distribution, and sale of prescription opioids nationally, regionally and in Clearfield County, in violation of the UTPCPL.

578. Clearfield County saw an increase in drug-related overdose deaths of 82% from 2016 to 2018; while the number dropped in 2017, from 2017 to 2018 the increase then spiked 300%.[284] Overdose deaths in the County from prescription opioids equaled or far exceeded the numbers from heroin and fentanyl for 2015, 2016, and 2017.[285]

579. Addiction metrics were also high. For instance, in 2016, Clearfield County had 1,057 residents covered by Medicaid with an Opioid Use Disorder (OUD) and 562 residents covered by Medicaid expansion with OUD.

580. Yet, despite these shocking numbers, Defendants have not changed their ways. According to the Pennsylvania Department of Health's Prescription Drug Monitoring Program, in the fourth quarter of 2018, Clearfield County had one of the highest rates of dispensation of Schedule II Opioids in the state.[286] Between 2016 and the third quarter of 2019, Clearfield County's rate of dispensations per 10,000 residents for opioids exceeded that of both Philadelphia and Allegheny counties.

581. According to the Clearfield County Coroner's office, between 2006 and 2019, there

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[284] Clearfield County Drug-Related Overdose Deaths, 2016-2018, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2020/02/DEA2018_Clearfield_CntyPgs.pdf.
[285] Pennsylvania DEA Opioid Threat Report 2018, *supra,* at 113.
[286] Pennsylvania Prescription Drug Monitoring Program, Interactive Data Report, https://www.health.pa.gov/topics/programs/PDMP/Pages/Data.aspx

have been double digit overdose-related deaths in 10 of those 14 years, with the most occurring in 2018.

582. The County's public health and safety opioid crisis clearly includes historically high incidences of opioid addiction and use disorder and of opioid-related deaths and non-fatal opioid overdoses. It also includes other adverse health effects of opioid addiction and use disorder including higher incidences of babies born with opiate withdrawal conditions, and an increase in new Hepatitis C infections caused by opiate injections.

583. The epidemic has also been accompanied by an high levels of opioid-related emergency room visits and hospitalizations; extensive provision of emergency response services by the ambulances, fire departments, and other County agencies in reviving and transporting overdose victims; and the expenditure of large amounts of resources by the police departments, District Attorney's office, Public Defender's office, County and local prison systems, Health Department, disability services, human services, and other departments and agencies providing health and related services to address increased crime and violence and family and social dysfunction linked to opioid use and addiction.

584. The drug naloxone (usually sold under the brand name Narcan) is a potentially life-saving medication that reverses the effect of opioids and is used to treat opioid overdoses that would otherwise be fatal. The County and entities therein have incurred costs related to the purchase of naloxone and/or the training required for its effective administration.

585. In many if not most cases of overdoses in the County, EMS is required to respond to emergency calls to rescue those suffering from the effects of opioid abuse. Although EMS bills patients for its services, its paramedics must provide care without regard to a patient's ability to pay. Consequently, the uncompensated care costs associated with treating opioid overdoses has ballooned.

586. Similarly, private hospitals and other medical providers, who are also statutory "persons in interest" for purposes of this public enforcement action, must absorb the tremendous costs associated with treating uninsured individuals suffering from opioid overdoses or opioid use disorder.

587. The costs for both County-funded and privately funded health, dental, and life insurance benefits have also grown in part because of the costs related to: (1) visits to doctor's offices when covered individuals and their family members visit to obtain unnecessary opioid prescriptions; (2) opioid addiction treatment for covered employees and their family members; (3) treatment for infectious diseases attributable to opioid use; and (4) medical care needed to treat opioid side effects, or the increases in the rates of coverage because of increases in costs and services due to the opioid epidemic, all of which has been caused by Defendants.

588. Both the County and private entities have incurred increased expenditures to provide addiction treatment services, such as medication assisted treatment (MAT), counseling, and other services.

589. Numerous agencies and private institutions have also paid for increased expenses related to homelessness and foster care services that arise, at least in part, from opioid addiction.

590. Opioid abuse is a threat to the health of not only County residents who have used opioids, but even those who have not. For example, opioid use during pregnancy can lead to neonatal abstinence syndrome (NAS) and interfere with a child's brain development, resulting in impairments of mental functioning and behavior. According to the latest data, for all maternal hospital stays involving substance use, almost half of these hospitalizations involved opioids.[287]

591. Opioid use can also lead to infectious diseases such as Hepatitis C virus (HCV) as

[287] Pennsylvania Health Care Cost Containment Council, http://www.phc4.org/reports/researchbriefs/opioids/121118/nr121118.htm.

a result of using needles to inject opioids.[288] If left untreated, HCV can result in liver cirrhosis, cancer, and end-stage liver disease. Incidences of HCV have increased due to the opioid epidemic.

592. Similarly, opioid abuse can lead to other health problems such as right-sided heart valve infections as a result of using needles to inject opioids. The incidence of right-sided heart valve infections has increased rapidly over the past decade as a consequence of the opioid epidemic.[289]

593. Residents and other affected persons in interest in or doing business in the County paid considerable sums for opioid prescriptions and incurred significant health care and other costs related to opioids during the period of Defendants' false and deceptive marketing, distribution, and sale of the drugs.

594. Defendants derived considerable revenue from these affected persons in interest during the period of Defendants' false and deceptive marketing, distribution, and dispensing of opioids. Defendants are liable by way of restoration and/or restitution for these costs and revenues.

595. The opioid epidemic is a growing threat to not only the County's public health but also its public safety, as a result of the dramatic increase in opioid-related crimes. Such crimes include sales and purchases of heroin and other opioids; theft of money or property to finance opioid addiction; theft of prescription opioids from friends, relatives or others; and crimes committed while under the influence of opioids. Opioid abuse has adversely impacted neighborhood public safety and well-being in the County.

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[288] *See, e.g.,* Sean Murphy *et al.*, Association Between Hepatitis C Virus and Opioid Use While in Buprenorphine Treatment: Preliminary Findings (2015) ("The prevalence of hepatitis-C-virus (HCV) infections is high among opioid-dependent individuals."), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638227/.

[289] M. Daubresse, *et al.*, Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013). Hospitalizations for Heart Infection Related to Drug Injection Rising Across the US, Science Daily (Sept. 1, 2016), https://www.sciencedaily.com/releases/2016/09/160901092818.htm.

596. The County's first responders have been required to expend considerable resources-- often at great personal risk-- in addressing the most severe harms associated with opioid addiction, not only from individuals committing violent and dangerous crimes to fuel their drug habits, but also from the risk of exposure to potentially deadly opioids like fentanyl.

597. In the rural areas of Pennsylvania like Clearfield County, opioids often go hand-in-hand with and methamphetamines, which has helped to fuel the rise of both dangerous drugs. For instance, many opioid addicts turn to meth as a holdover drug to ease their withdrawal symptoms.[290] Thus the rise of the use and abuse of methamphetamines plaguing Clearfield County is also related to Defendants' violations of the UTPCPL.

598. This has predictable, but tragic, results. For instance, in 2018, Officer Patrick Straub of the Dubois City Police Department, while off-duty, was struck head on and killed by a driver who had "off the charts" levels of methamphetamine and amphetamine in his system. Additionally, opioid addicts also make and sell meth in order to support their addiction.

599. Opioid misuse and opioid use disorder also have a significant economic impact because they lead to unscheduled worker absenteeism, reduced productivity, hospitalizations that cost days of work, unemployment, and even exits from the labor force. On average, substance use disorder has been estimated to reduce total per-person productivity by 17 percent.

600. The annual estimated wage losses associated with opioid use disorder in Clearfield County is $5,126,006.60; the sum of lost lifetime earnings due to fatal opioid overdose annually for Clearfield County is $13,639,100.45.[291]

601. All of these circumstances – opioid deaths, opioid-related emergency department

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[290] Jason Nark, Meth Goes Hand-in-Hand with Opioids in Much of Pennsylvania, The Philadelphia Inquirer (Dec. 19, 2018), https://www.inquirer.com/news/meth-rural-opioid-overdose-pennsylvania-dea-drugs-addiction-20181219.html.

[291] Pennsylvania Opioid Data Dashboard- Economic Impact, https://data.pa.gov/stories/s/Pennsylvania-Opioids-Impact-on-Economy/enh4-nazt

visits and hospital admissions, drug overdoses requiring naloxone, increased NAS, the rise in Hepatitis C, increased use of police resources, increased risks for first responders, and the economic impact of addiction and treatment, as well as widespread, severe family and social dysfunction as discussed above – are recognized, direct, and quantifiable results of the adverse public health and safety impact on Clearfield County due to the opioid epidemic, which has been caused by Defendants' actions.

IX. ANY STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING THESE AS A DEFENSE

A. Nullum Tempus

602. Any potential statute of limitations is inapplicable here pursuant to the doctrine of *nullum tempus occurrit regi.*

603. This public enforcement action is brought by the District Attorney in the name of the Commonwealth, as authorized by statute. Under the doctrine of *nullum tempus,* statutes of limitations do not apply to an action brought by the Commonwealth, unless the statute limits the governments right to sue, which the UTPCPL does not.

B. Continuing Conduct

604. Any potential statute of limitations is also inapplicable because the Plaintiff continues to suffer hard from the unlawful actions by Defendants.

605. The continued tortious conduct by Defendants causes a repeated and continuous injury. The damages have not occurred all at once, but have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Though the Plaintiff has made efforts to abate the damages it and other person in interest are suffering, the wrongdoing has not ceased and, this, the damages resulting from the Defendants' violation of the UTPCPL remain and the conduct causing the damages remains unabated.

C. Equitable Estoppel

606. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the Commonwealth, that they were undertaking efforts to comply with their legal obligations to help prevent the diversion of prescription opioids. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the Commonwealth, that they were working to curb the opioid epidemic.

607. For example, as detailed above, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

608. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

609. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in the *Masters Pharmaceuticals* litigation, which made the following statements:[292]

- HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.
- DEA regulations that have been in place for more than 40 years require distributors to

[292] *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

report suspicious orders of controlled substances to DEA based on information readily available to them, including a pharmacy's placement of unusually frequent or large orders.

- Distributors take their duty to report suspicious orders seriously, utilizing both computer algorithms and human review to detect suspicious orders based on information that is available to them in the ordering process.
- Distributors monitor report abnormal behavior by pharmacies, such as refusing to provide business contact information or insisting on paying in cash.

610. Through the above statements made on their behalf by their trade associations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but affirmatively represented that their conduct was in compliance with those obligations.

611. Likewise, the Pharmacy Defendants also misrepresented their compliance with their duties to monitor, report, and halt suspicious orders, as well as their efforts to safely dispense opioids in a manner that avoids or minimizes diversion.

612. The Manufacturer Defendants distorted the meaning or import of studies that they cited and offered them as evidence for propositions the studies did not support. As detailed above, these Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community using literature and materials that were created at their direction and paid for by Defendants. The Manufacturer Defendants provided the medical community and the public at large with false and misleading information about strategies that they knew were ineffectual to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. They also spent millions of dollars on a multi-year misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

613. The medical community, consumers, and the Commonwealth were duped by the

Manufacturer Defendants' campaign to misrepresent and conceal the truth about opioids that they were aggressively pushing in the Commonwealth generally and Clearfield County in particular.

614. The Commonwealth reasonably relied on Defendants' affirmative statements and misrepresentations regarding their purported compliance with their obligations under the law and consent orders.

D. Intentional Concealment

615. Alternatively, the Commonwealth's claims are subject to equitable tolling because the Defendants knowingly and intentionally concealed the facts alleged herein. The Defendants knew of the wrongful acts set forth above, had material information pertinent to their discovery, and concealed them from the Plaintiff. As a result of the Defendants' conduct, Plaintiff did not know, and could not have known through the exercise of reasonable diligence, of its cause of action.

616. The Defendants deliberately took steps to conceal their misconduct in the deceptive marketing and oversupply of opioids, all of which fueled the opioid epidemic.

617. As set forth above, the Defendants deliberately concealed their actions through the use of Front Groups purporting to be patient advocacy and professional organizations, public relations companies hired to work with the Front Groups, and through paid KOLs. All of these were a means to covertly control messaging, influence prescribing practices, deceive the public regarding the safety and efficacy of opioids, and drive sales. The Defendants also concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations, and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators. prescribers and the public at large. These efforts include influencing the WHO guidelines regarding the use of opioids to their own benefit. They concealed the addictive nature and dangers associated with opioid use and

denied blame for the resultant epidemic, instead placing the blame on addicts and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that their misleading and unfounded statements about the risks, safety, and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Defendants' deceptions deprived the Plaintiff of actual or implied knowledge of facts sufficient to put the Plaintiff on notice of potential claims.

618. Defendants also concealed the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement, and affirmatively seeking to convince the public that they had fulfilled their legal duties to monitor report and halt suspicious orders and were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion. Their repeated misrepresentations misled regulators, prescribers, and the public, including the Plaintiff, and deprived the Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

619. As a result of the foregoing, Plaintiff did not discover the nature, scope, and magnitude of the Defendants' misconduct and its full impact on Clearfield County, nor could Plaintiff have acquired such knowledge earlier through the exercise of reasonable diligence.

620. The Defendants' campaign to misrepresent and conceal the truth about opioids that they were aggressively manufacturing, distributing, and dispensing into Clearfield County deceived the medical community, consumers, and the Plaintiff.

621. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff. Plaintiff did not know, and did not have the means to discover, the truth, due to Defendants' acts and omissions.

622. The Plaintiff reasonably relied on Defendants' affirmative statements regarding

their purported compliance with their obligations under the law and consent orders.

623. The purposes of the statutes of limitations period are satisfied because the Defendants cannot claim prejudice due to late filing where Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which the Defendants knowingly concealed.

624. In light of their statements to the media, in legal filings, and settlements, it is clear that the Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

625. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only the Defendants and their agents knew or could have known about Defendants' unlawful failures, described above, because the Defendants made deliberate efforts to conceal their conduct. As a result, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

CLAIMS FOR RELIEF

COUNT I

VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 P.S. §§ 201-1 – 201-9.3 (AGAINST ALL DEFENDANTS)

626. The Commonwealth incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

627. The UTPCPL prohibits persons from employing "[u]nfair methods of competition" and "unfair or deceptive acts or practices," which are defined to include, *inter alia*, the following conduct:

a. "Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services." 73 P.S. § 201-2(4)(ii);

b. "Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . ." 73 P.S. § 201-2 (4)(v); or

c. "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 P.S. § 201-2 (4)(xxi).

628. Defendants are persons under the UTPCPL.

629. Defendants violated the UTPCPL in that their conduct as alleged herein caused a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of the drugs at issue.

630. Defendants violated the UTPCPL in that by their conduct as alleged herein they represented that the drugs at issue had sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have.

631. Defendants violated the UTPCPL in that by their conduct as alleged herein Defendants engaged in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

632. Under Pennsylvania law, an act or practice is unfair or deceptive if it had the capacity to deceive, or was likely to deceive, a substantial portion of the public, and was likely to make a difference in the purchasing decision.

633. Defendants' conduct as alleged herein constitutes unfair or deceptive acts or practices in violation of the above provisions of the UTPCPL in that:

a. At all relevant times, Defendants directly, or indirectly through their Third-Party Allies, made and disseminated, or caused to be made and disseminated, materially false and misleading statements directed at the Defendants' target audiences in Clearfield County, which included physicians, consumers, and PBMs responsible for

selecting the drugs covered by the County's health coverage plans and included on pharmacy formularies;

b. These false and misleading statements by the Defendants directly, or indirectly through their Third-Party Allies, were specifically intended to promote the sale and use of opioids to treat chronic pain to members of their target audiences in Clearfield County;

c. At all relevant times, the Defendants directly, or indirectly through their Third-Party Allies, made statements that omitted material facts to promote the sale and use of opioids to treat chronic pain;

d. Defendants directly, or indirectly through their Third-Party Allies, repeatedly failed to disclose or minimized material facts about the risks of opioids, including the life-threatening risks of abuse, misuse, and addiction, and their risks compared to alternative treatments. These omissions were directed at and affected all the target audiences in the Clearfield County;

e. Such material omissions by Defendants directly, or indirectly through their Third-Party Allies, were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids misleading, creating a false impression of the risks, benefits, and superiority of opioids for treatment of chronic pain;

f. At all relevant times, Defendants, directly or indirectly through their Third-Party Allies, made and disseminated the foregoing misleading and deceptive statements and omissions through an array of marketing channels including, but not limited to: in-person and other forms of detailing; speaker events, including meals, conferences, and teleconferences; CMEs; journal articles and studies; advertisements; and brochures

and other patient education materials;

g. These materially false and misleading statements and omissions by the Defendants directly, or indirectly through their Third-Party Allies, were widely disseminated to the medical community and the public in Clearfield County, including the target audiences alleged above;

h. Defendants knew or should have known that their marketing and promotional efforts created a misleading impression of the risks, benefits and purported superiority of opioids;

i. Defendants intentionally misrepresented their compliance with their affirmative legal obligations to monitor, report, and halt suspicious orders of prescription opioids, and misrepresented their efforts to prevent diversion of and addiction to opioids;

j. Defendants knew or should have known that their deceptive and misleading statements regarding the effectiveness of their monitoring systems and their efforts to prevent diversion and addiction created and or enhanced the misleading impression that opioids were safe and effective, and that Defendants were providing to law enforcement the names of prescribers and individuals that they knew or should have known to be facilitating the over-prescription and diversion of opioids in Clearfield County, while simultaneously providing opioids to those same prescribers and/or individuals;

k. Defendants' conduct, including their deceptive representations and concealments of material fact, created a significant likelihood of confusion and/or misunderstanding as to the safety, efficacy, and risks of opioids, including the risks associated with the use of opioids for chronic pain;

l. Defendants' conduct had a tendency to deceive a substantial segment of the target

audiences in Clearfield County, and their misrepresentations and concealments of material facts were likely to be misinterpreted in a misleading way; and

m. Defendants' acts and practices – taken individually and collectively – were likely to make a difference in the prescribing decisions of doctors; usage and purchasing decisions of patients; the formulary decisions of PBMs; and the payment decisions of end-payors, because their misrepresentations and other wrongful acts were specifically designed to mislead and convince these individuals and groups that opioids were safe and superior to alternative treatments for chronic pain.

634. As a direct result of their foregoing acts and practices in violation of the UTPCPL, Defendants have received, and will continue to receive, income, profits, and other benefits, which they would not have received if they had not engaged in violations of the UTPCPL as alleged herein.

635. As a direct result of Defendants' foregoing acts and practices in violation of the UTPCPL, Clearfield County and its affected residents and other persons in interest have suffered substantial injury as alleged herein.

636. As direct result of their foregoing acts and practices in violation of the UTPCPL, Defendants have caused Clearfield County and its affected residents and other persons in interest to incur and continue to incur enormous costs and expenses related to the purchase of opioids and the consequences of dealing with the opioid epidemic.

637. As Defendants' foregoing acts and practices in violation of the UTPCPL were a substantial factor in the creation of the opioid epidemic in Clearfield County, as alleged herein, Defendants are responsible for restoring to the County and its affected residents and other persons in interest the enormous costs and expenses which the County and such affected persons in interest have incurred and will incur in responding to the epidemic and otherwise redressing the injuries

they have suffered.

638. The Commonwealth seeks all legal and equitable relief as allowed by law, including, *inter alia,* injunctive relief for Defendants' violations of the UTPCPL, as authorized under § 73-201-4. Specifically, the Commonwealth seeks an injunction requiring Defendants to cease all false or misleading promotional, marketing, and advertising activities regarding the use of prescription opioids for chronic pain, and to inform the medical community and the public of the true risks of daily, long-term opioid use.

639. The Commonwealth has reason to believe, based on the facts alleged herein, that the Defendants' omissions, misrepresentations, and practices related to the marketing, advertisement, promotion, distribution, and sale of opioids have violated, and will continue to violate, the UTPCPL, absent the grant of an injunction.

640. Unless restrained by this Court, the Defendants will likely continue to engage in the methods, acts, or practices which have a likelihood to deceive, mislead and confuse the public with respect to the use of opioids for chronic pain, all in violation of the UTPCPL.

641. These ongoing, and likely future violations by Defendants of the UTPCPL are contrary to the public interest, thereby necessitating an injunction to restrain and prevent further such misconduct by the Defendants.

642. Pursuant to Section 4 of the UTPCPL, 73 P.S. § 201-4, and due to their respective violations of the UTPCPL set out in this Complaint, the Defendants should further be ordered and directed by the Court to restore to the County and other persons in interest in or doing business in the County, including any health plans or third-party payors administering prescription drug benefits who paid opioid-related claims, any moneys or property, real or personal, which may have been acquired by Defendants by means of their violations of the UTPCPL, including the costs of the opioids themselves, and which the County and other persons in interest in or doing business in

the County have been caused to expend or will be required to expend so as to treat, address or otherwise remediate the negative consequences of dealing with opioid addiction and other economic and public health consequences.

643. The Commonwealth also seeks restoration and/or restitution to the County for the costs of increased services directly associated with opioid addiction, fatal and non-fatal overdoses and other adverse health and public safety conditions, including the increased emergency response costs, hospitalization, and other costs attributable to the Defendants' violations of the UTPCPL.

644. The Commonwealth further seeks and by way of restoration and/or restitution an order directing Defendants to disgorge all monies acquired or retained by Defendants as a result of their violations of the UTPCPL in the County and their violations outside the County which impacted the County and other persons in interest in or doing business in the County.

645. Section 8 of the UTPCPL, 73 P.S. § 201-8, also empowers the Court to impose a civil penalty not exceeding $1,000 for each willful violation of the statute and a penalty not exceeding $3,000 for each violation where the victim is sixty years of age or older.

646. The Commonwealth is entitled to the Court's assessment against Defendants of an appropriate civil penalty for each violation of the UTPCPL by them. The Commonwealth is also entitled to all other damages authorized by the statute, including treble damages.

647. The monies demanded herein are in excess of $50,000, exclusive of interests and costs.

COUNT II

CIVIL CONSPIRACY
(AGAINST ALL DEFENDANTS)

648. The Commonwealth incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

649. As set forth above, Defendants have engaged in a civil conspiracy to promote their

false and/or misleading statements and omissions regarding the efficacy and safety of opioids and to avoid or misrepresent their compliance with their legal duties to prevent diversion of opioids in Clearfield County, all in violation of the UTPCPL.

650. Defendants acted tortiously in agreement and/or in concert with each other and/or in pursuit of a common design, and/or Defendants' knew that each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in such conduct.

651. Defendants performed overt acts in furtherance of this conspiracy.

652. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in furtherance of the conspiracy's objective(s) are ongoing and/or do not full outside any applicable statute limitations.

653. Defendants acted with agreement and a common understanding or design to commit unlawful acts and/or lawful acts unlawfully, as alleged above, and acted purposely without a reasonable or lawful excuse, to create the injuries alleged in this Complaint.

654. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

655. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

656. Plaintiff seeks all legal and equitable relief as allowed by Pennsylvania law, including injunctive relief, restitution/restoration, disgorgement of profits, all other damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

657. The monies demanded herein are in excess of $50,000, exclusive of interests and

costs.

WHEREFORE, the District Attorney, in the name of the Commonwealth, respectfully requests that the Court award the following relief against Defendants, jointly and severally, as follows:

a. Enter an order enjoining Defendants from continuing to violate the UTPCPL now and in the future through their deceptive marketing and failure to comply with their duties to prevent diversion, and directing that Defendants take affirmative steps to provide accurate information the public as to the nature and consequences of opioid drugs and take affirmative steps to demonstrate to this Court that they each have in place an effective system for monitoring, reporting, and halting suspicious orders in this County;

b. Enter an order requiring Defendants to restore to the County and other affected persons in interest in or doing business in the County, including any health plan providers who paid opioid-related claims, any moneys or property, real or personal, which Defendants may have acquired by means of their violations of the UTPCPL, including the costs of the opioids themselves, and which the County has been caused to expend or will be required to expend so as to remediate or otherwise address the negative consequences of dealing with opioid addiction and consequences attributable to Defendants' violations;

c. Enter an order requiring Defendants to restore to the County the costs of increased services directly associated with opioid addiction, fatal and non-fatal overdoses and other adverse health and public safety conditions, including the increased emergency response costs, hospitalization, and other costs attributable to the Defendants' practices, as set forth in this Complaint;

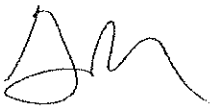
d. Enter an order directing Defendants to disgorge all monies acquired or retained by Defendants as a result of their violations in the County and their violations outside the County which impacted the County and other persons in interest in or doing business in the County;

e. Enter an order awarding the Commonwealth civil penalties under 73 P.S. § 201-8 against Defendants in a sum not exceeding $1,000 for each willful violation of the statute and not exceeding $3,000 for each violation where the victim is sixty years of age or older; and

d. Such other and further relief as the Court deems just and proper.

Dated: August 20, 2020

Respectfully submitted,



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Attorneys for Plaintiffs

VERIFICATION

I, Ryan P. Sayers, District Attorney of Clearfield County, hereby state that I have authority to make this verification on behalf of Plaintiff. The averments in the Complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements made herein are subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities.

Date: August, 10 2020

Ryan P. Sayers
District Attorney of Clearfield County

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Attorneys for Defendant
Cardinal Health, Inc.

IN THE COURT OF COMMON PLEAS OF CLEARFIELD COUNTY
FORTY-SIXTH JUDICIAL DISTRICT OF PENNSYLVANIA

DISTRICT ATTORNEY OF CLEARFIELD COUNTY, Plaintiff, vs. PURDUE PHARMA LP, *et al.* Defendants.	CIVIL DIVISION No. 2020-1026-CD

PRAECIPE FOR ENTRY OF APPEARANCE

TO: THE CLERK OF THE PROTHONOTARY:

Kindly enter the appearance of Douglas K. Rosenblum as counsel for Defendant, Cardinal Health, Inc., in the above-captioned matter.

PIETRAGALLO GORDON ALFANO
BOSICK & RASPANTI, LLP

By: _____
Marc S. Raspanti, Esquire - PA Atty. ID #41350
Douglas K. Rosenblum, Esquire - PA Atty. ID #90989
Attorneys for Defendant
Cardinal Health, Inc.

Date: September 15, 2020

#5512134/1

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Attorneys for Defendant Cardinal Health, Inc.

IN THE COURT OF COMMON PLEAS OF CLEARFIELD COUNTY FORTY-SIXTH JUDICIAL DISTRICT OF PENNSYLVANIA

DISTRICT ATTORNEY OF CLEARFIELD COUNTY, Plaintiff, vs. PURDUE PHARMA LP, *et al.* Defendants.	CIVIL DIVISION No. 2020-1026-CD

CERTIFICATE OF SERVICE

I, Douglas K. Rosenblum, Esquire, hereby certify that on this 11th day of September 2020, I caused a true and correct copy of this Praecipe for Entry of Appearance to be served upon the following via the United States First-Class Mail:

Harris L. Pogust, Esquire (Atty I.D. No. 52721)
Tobias L. Millrood, Esquire (Atty I.D. No. 77764)
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Attorneys for Plaintiff, District Attorney of Clearfield County

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP

By: _____

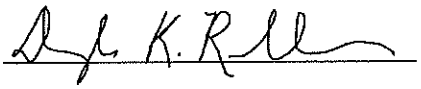
Marc S. Raspanti, Esquire
Douglas K. Rosenblum, Esquire
Attorneys for Defendant
Cardinal Health, Inc.

Date: September 15, 2020

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Case Records Public Access Policy of the Unified Judicial System of Pennsylvania* that require filing confidential information and documents differently than non-confidential information and documents.

Submitted by: Douglas K. Rosenblum

Signature: 

Name: Douglas K. Rosenblum

Attorney No. (if applicable): 90989

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IN THE COURT OF COMMON PLEAS OF CLEARFIELD COUNTY
FORTY-SIXTH JUDICIAL DISTRICT OF PENNSYLVANIA

DISTRICT ATTORNEY OF CLEARFIELD COUNTY, Plaintiff, vs. PURDUE PHARMA LP, *et al.* Defendants.	CIVIL DIVISION No. 2020-1026-CD

PRAECIPE FOR ENTRY OF APPEARANCE

TO: THE CLERK OF THE PROTHONOTARY:

Kindly enter the appearance of Marc S. Raspanti as counsel for Defendant, Cardinal Health, Inc., in the above-captioned matter.

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP

By: Marc S. Raspanti/DKR
Marc S. Raspanti, Esquire - PA Atty. ID #41350
Douglas K. Rosenblum, Esquire - PA Atty. ID #90989
Attorneys for Defendant
Cardinal Health, Inc.

Date: September 15, 2020

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Attorneys for Defendant Cardinal Health, Inc.

IN THE COURT OF COMMON PLEAS OF CLEARFIELD COUNTY FORTY-SIXTH JUDICIAL DISTRICT OF PENNSYLVANIA

DISTRICT ATTORNEY OF CLEARFIELD COUNTY, Plaintiff, vs. PURDUE PHARMA LP, *et al.* Defendants.	CIVIL DIVISION No. 2020-1026-CD

CERTIFICATE OF SERVICE

I, Marc S. Raspanti, hereby certify that on this 15th day of September 2020, I caused a true and correct copy of this Praecipe for Entry of Appearance to be served upon the following via the United States First-Class Mail:

Harris L. Pogust, Esquire (Atty I.D. No. 52721)
Tobias L. Millrood, Esquire (Atty I.D. No. 77764)
Gabriel C. Magee, Esquire (Atty I.D. No. 311646)
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Attorneys for Plaintiff, District Attorney of Clearfield County

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP

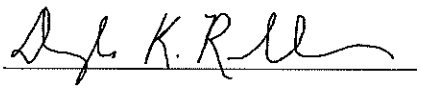
By: Marc S. Raspanti/DKR
Marc S. Raspanti, Esquire
Douglas K. Rosenblum, Esquire
Attorneys for Defendant
Cardinal Health, Inc.

Date: September 15, 2020

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Case Records Public Access Policy of the Unified Judicial System of Pennsylvania* that require filing confidential information and documents differently than non-confidential information and documents.

Submitted by: Douglas K. Rosenblum

Signature: 

Name: Douglas K. Rosenblum

Attorney No. (if applicable): 90989

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA OFFICE OF JUDICIAL SUPPORT

RULE OF CIVIL PROCEDURE NO. 236

Delaware County, Pennsylvania et al,
Plaintiff

v.

No. CV-2017-008095

Purdue Pharma L.P. et al,
Defendant.

NOTICE IS GIVEN UNDER PENNSYLVANIA RULE OF CIVIL PROCEDURE NO. 236 THAT AN ORDER IN THE ABOVE CASE HAS BEEN ENTERED ON 09-24-2020.

SIGNED 2020-09-22

PER Judge Barry Dozor

TIME AND LEGAL LIABILITY DO NOT PERMIT THE OFFICE OF JUDICIAL SUPPORT TO GIVE DOCKET INFORMATION BY TELEPHONE.

NO EXCEPTIONS!

PUBLIC ACCESS INFORMATION: www.co.delaware.pa.us

CC: POGUST, HARRIS L, BARRETT, MICHAEL F, BELEFONTE, CARMEN P, MONGELUZZI , ROBERT J, Trent B Mircle, WIGRIZER, STEVEN G, ABERNETHY, DAVID F, ERIC CORY ROSENBERG, SMITH , STUART STRICKLAND, REED , STEVEN A, Caroline Power, CAPPELLI , JOSEPH J, DESIDERATO , JERRY R, IMPERATRICE III, ROCCO P, RASPANTI , MARC S, Douglas Rosenblum, MCCLURE , SHANNON E, SCHACK , LOUIS W, NICHOLAS , ROBERT A, NEWCOMER , MATTHEW TODD, KENDALL, CAROLYN H, Brian J Taylor, Adam S. Tolin, Ryan Z Watts, Anthony J Franze, Ingo W Sprie, Jr., HELLER , GREGORY B, PLATT II, WILLIAM H, DONAGHUE, HUGH A, PERRUCCI , CHRISTIAN M, ROBERT M DONCHEZ, ROBERT A FREEDBERG, Ashley W Hardin, F. Lane Heard, Steven M Pyser, Enu A Mainigi, ALLAN KANNER, Kevin B Collins, Steven Winkelman, NOFER , PAUL G, Augusta M ONeill, Christopher Boisvert, Neil A Hlawatsch, Shawn T. Cobb, HAVILAND , DONALD E, John T. Ryan, LEVINE , JAN P, Ronni Fuchs, Logan N. Anderson, W. Steven Berman, W. Steven Berman, Michael J. Boni, Michael J. Boni,

Clearfield County Courhouse CV-2017-008095
COURT OF COMMON PLEAS PROTHONOTARY
230 East Market Street
P.O. BOX 549
Clearfiled PA 16830

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

ORDER

AND NOW, this 22 day of September, 2020, upon notification provided consistent with this Court's March 26, 2018 and September 27, 2018 Orders, and by lack of objection by Plaintiffs, it is hereby **ORDERED** and **DECREED** as follows:

1. The following action is coordinated before the Court of Common Pleas of Delaware County and shall be transferred to this Court pursuant to Pennsylvania Rule of Civil Procedure 213.1 for all pretrial proceedings:

    a. *District Attorney of Clearfield County v. Purdue Pharma, L.P., et al.* (Clearfield CCP, NO. 2020-1026).

2. Pursuant to Pennsylvania Rule of Civil Procedure 213.1(b), all proceedings in these actions being transferred to the Delaware County Court of Common Pleas for coordination are stayed until the completion of their transfer to this Court.

3. Pursuant to Pennsylvania Rule of Civil Procedure 213.1(e), the Delaware County Office of Judicial Support shall immediately send a certified copy of this Order to the Clearfield County Court of Common Pleas Prothonotary, and a notice to all Plaintiffs and

Defendants of this Order immediately upon its entry. Defendants shall also serve this Order on counsel for all parties in the actions set forth in Paragraphs 1(a)-(d).

4. All parties shall bear their own costs in connection with coordination and the litigation of the coordinated actions.

BY THE COURT:

J. Barry C. Dozor

CERTIFIED A TRUE AND CORRECT
COPY FROM THE RECORD
THIS 24th DAY OF Sept A.D 2020
MARY J. WALK, ESQUIRE, DIRECTOR
OFFICE OF JUDICIAL SUPPORT
Jennifer Stuckler

FILED
09-24-2020 10:27 AM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

RYAN P. SAYERS (Atty I.D. No. 313682)
DISTRICT ATTORNEY OF CLEARFIELD COUNTY
Clearfield County Courthouse Annex
230 East Market Street
Clearfield, PA 16830
rsayers@clearfieldco.org

POGUST MILLROOD, LLC
Harris L. Pogust, Esquire (Atty I.D. No. 52721)
Tobias L. Millrood, Esquire (Atty I.D. No. 77764)
Gabriel C. Magee, Esquire (Atty I.D. No. 311646)
161 Washington St., Suite 940
Conshohocken, PA 19428
(610) 941-4204
gmagee@pogustmilrood.com

Attorneys for Plaintiff

DISTRICT ATTORNEY OF CLEARFIELD COUNTY	:	COURT OF COMMON PLEAS CLEARFIELD COUNTY, PA
	:	
	:	CIVIL ACTION NO: 2020-1026-CD
Plaintiff	:	
v.	:	
	:	
PURDUE PHARMA L.P. et. al.,	:	
	:	
Defendants	:	

PRAECIPE TO REINSTATE COMPLAINT

To the Prothonotary of Clearfield County, Pennsylvania:

Kindly Reinstate the Complaint in the above captioned matter. The case is in excess of Fifty Thousand Dollars ($50,000.00)

Respectfully submitted,

POGUST MILLROOD, LLC

Dated: October 12, 2020

SHERIFF'S OFFICE OF CLEARFIELD COUNTY

Michael Churner
Sheriff

Robert Thomas
Chief Deputy

Gary A Knaresboro
Solicitor

Cynthia Butler-Aughenbaugh
Office Manager

DISTRICT ATTORNEY OF CLEARFIELD COUNTY
vs.
PURDUE PHARMA L.P. (et al.)

Case Number
2020-1026-CD

SHERIFF'S RETURN OF SERVICE

09/08/2020 Sheriff Michael Churner, being duly sworn according to law, deposes and says, the Sheriff of Allegheny County was deputized to serve the within Complaint & Notice on GIANT EAGLE DRUGS.

09/08/2020 Sheriff Michael Churner, being duly sworn according to law, deposes and says, the Sheriff of Blair County was deputized to serve the within Complaint & Notice on AHOLD USA, INC.

09/08/2020 Sheriff Michael Churner, being duly sworn according to law, deposes and says, the Sheriff of Cumberland County was deputized to serve the within Complaint & Notice on THE GIANT COMPANY, LLC.

09/08/2020 Sheriff Michael Churner, being duly sworn according to law, deposes and says, the Sheriff of Allegheny County was deputized to serve the within Complaint & Notice on THE GIANT COMPANY, LLC.

09/09/2020 02:42 PM - The requested Complaint & Notice served by the Sheriff of Blair County upon DAVID MODICO, MANAGER, who accepted for VALUE DRUG CO, at 195 THEATER DRIVE, DUNCANSVILLE, PA 16635. BLAIR COUNTY, Sheriff, Return of Service attached to and made part of the within record.

09/11/2020 04:44 PM - The requested Complaint & Notice served by the Sheriff of Cumberland County upon JORDAN SALISBURY, SECURITY OFFICER, who accepted for THE GIANT COMPANY, LLC, at 1149 HARRISBURG PIKE, CARLISLE, PA 17013. CUMBERLAND COUNTY, Sheriff, Return of Service attached to and made part of the within record.

09/11/2020 04:44 PM - The requested Complaint & Notice served by the Sheriff of Cumberland County upon JORDAN SALISBURY, SECURITY OFFICER, who accepted for AHOLD USA, INC, at 1149 HARRISBURG PIKE, CARLISLE, PA 17013. CUMBERLAND COUNTY, Sheriff, Return of Service attached to and made part of the within record.

09/21/2020 Sheriff Michael Churner, being duly sworn according to law, deposes and says, the requested service returned by the Sheriff of Allegheny County "Not Served", see attached return of non-service.

ALLEGHENY CO. SENT BACK COMPLAINT. NOT A GOOD ADDRESS.

09/21/2020 Sheriff Michael Churner, being duly sworn according to law, deposes and says, the requested service returned by the Sheriff of Allegheny County "Not Served", see attached return of non-service.

ADDRESS IS NOT ALLEGHENY COUNTY

SHERIFF COST: $139.00

SO ANSWERS,

October 09, 2020

MICHAEL CHURNER, SHERIFF

FILED
01 KSI 2541pm
OCT 09 2020
NOCC
BRIAN K. SPENCER
PROTHONOTARY & CLERK OF COURTS

COSTS

DATE	CATEGORY	MEMO	CHK #	DEBIT	CREDIT
09/08/2020	Advance Fee	Advance Fee	8915	$0.00	$139.00
09/08/2020	RDR			$9.00	$0.00
10/09/2020	Deputization			$27.00	$0.00
10/09/2020	Postage			$10.00	$0.00
10/09/2020	Service			$9.00	$0.00
10/09/2020	Service (Additional Defendant)			$12.00	$0.00
10/09/2020	Not Found			$10.00	$0.00
10/09/2020	Surcharge			$50.00	$0.00
10/09/2020	Mileage			$12.00	$0.00
				$139.00	**$139.00**

BALANCE: **$0.00**

SHERIFF'S OFFICE OF CUMBERLAND COUNTY

Ronny R Anderson
Sheriff

Jody S. Smith
Chief Deputy

Richard W Stewart
Solicitor

District Attorney of Clearfield County vs. Ahold USA, Inc. (et al.)	**Case Number** 2020-1026-CD

SHERIFF'S RETURN OF SERVICE

09/11/2020 04:44 PM - Deputy Thomas Somers, being duly sworn according to law, served the requested Complaint & Notice by handing a true copy to a person representing themselves to be Jordan Salisbury, Security Officer, who accepted as "Adult Person in Charge" for Ahold USA, Inc. at 1149 Harrisburg Pike, Middlesex Townhip, Carlisle, PA 17013.

THOMAS SOMERS, DEPUTY

09/11/2020 04:44 PM - Deputy Thomas Somers, being duly sworn according to law, served the requested Complaint & Notice by handing a true copy to a person representing themselves to be Jordan Salisbury, Security Officer, who accepted as "Adult Person in Charge" for The Giant Company, LLC at 1149 Harrisburg Pike, Middlesex Township, Carlisle, PA 17013.

THOMAS SOMERS, DEPUTY

SHERIFF COST: $34.95

SO ANSWERS,

RONNY R ANDERSON, SHERIFF

September 14, 2020

NOTARIAL SEAL
CLAUDIA A. BREWBAKER, NOTARY PUBLIC
Carlisle Boro, Cumberland County
My Commission Expires April 4, 2021

NOTARY

Affirmed and subscribed to before me this 13 day of September, 2020

SHERIFF'S OFFICE OF BLAIR COUNTY

James E. Ott
Sheriff

Nathan Karn
Solicitor

Christopher Tatar
Chief Deputy

DISTRICT ATTORNEY OF CLEARFIELD COUNTY
vs.
PURDUE PHARMA L P (et al.)

Case Number
2020-GN-80148 T

SHERIFF'S RETURN OF SERVICE

09/15/2020 Advance Fee

09/15/2020 02:42 PM - DEPUTY JOSHUA CHERISH, BEING DULY SWORN ACCORDING TO LAW, DEPOSES AND SAYS, THE COMPLAINT IN CIVIL ACTION (CICA) WAS SERVED TO @ACCEPTED BY DAVID MODICO/MANAGER, WHO ACCEPTED AS ADULT IN CHARGE AT THE TIME OF SERVICE TO WIT, VALUE DRUG CO AT 195 THEATER DRIVE, DUNCANSVILLE, PA 16635.

Joshua J Cherish
JOSHUA CHERISH, DEPUTY

SO ANSWERS,

James E Ott
JAMES E. OTT, SHERIFF

September 25, 2020

COSTS

DATE	CATEGORY	MEMO	CHK #	DEBIT	CREDIT
09/15/2020	Advance Fee	Advance Fee	8913	$0.00	$150.00
09/15/2020	Service			$33.00	$0.00
09/15/2020	Surcharge			$10.00	$0.00
09/25/2020	Affidavits			$2.00	$0.00
09/25/2020	Notary Fee			$5.00	$0.00
09/25/2020	Mileage			$25.00	$0.00
09/25/2020	Refund	(PAID 09/25/2020)	40211	$75.00	$0.00
				$150.00	**$150.00**

BALANCE: **$0.00**

Commonwealth of Pennsylvania - Notary Seal
Janet Lee Smith, Notary Public
Blair County
My commission expires August 16, 2024
Commission number 1243488
Member, Pennsylvania Association of Notaries

NOTARY

Affirmed and subscribed to before me this
25TH day of SEPTEMBER, 2020

Janet Lee Smith

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
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BY THE COURT:

J. Barry C. Dozor

DISTRICT ATTORNEY OF CLEARFIELD COUNTY Plaintiff, v. PURDUE PHARMA L.P., et al., Defendants.	:	COURT OF COMMON PLEAS CLEARFIELD COUNTY, PA CIVIL ACTION – LAW NO. 2020-01026-CD

ACCEPTANCE OF SERVICE

I hereby accept service of the Complaint of the District Attorney of Clearfield County on behalf of Defendants Mallinckrodt LLC and SpecGx LLC and certify that I am authorized to do so.

Date: September 1, 2020

Signed: _____

Edward T. Butkovitz, Esquire
KLEINBARD LLC
Three Logan Square
1717 Arch Street, 5th Floor
Philadelphia, PA 19103
(215) 568-2000